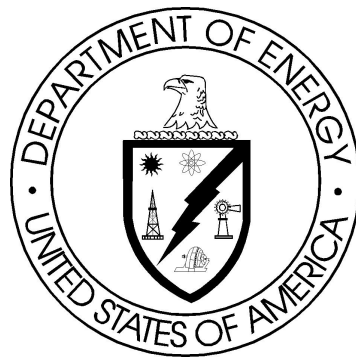


**Guidance for the Review
of TWRS Privatization Contractor
Initial Safety Assessment Submittal Package**



December 1997

Office of Radiological, Nuclear, and Process
Safety Regulation for TWRS Privatization Contractors

Richland Operations Office
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PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the TWRS Privatization Request for Proposal (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months will be used by the Contractors to develop the Part-A products and four months will be used by DOE to develop views, for input into DOE's Part B Contractor selections, of the Contractors' ability to implement integrated safety management and evaluate Contractor products developed under integrated safety management.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and integrated safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS

Privatization Contractors (referred to as the Policy) and implemented through the document entitled Memorandum of Agreement for The Execution of Radiological, Nuclear, and Process Safety Regulation of The TWRS Privatization Contractors (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, DOE Richland Office (RL); the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of the DOE regulating program.

The authority of the RU to regulate the TWRS Privatization Contractors is derived from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents (listed below), from the MOA, which are incorporated into the Contracts. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices of the regulatory authority.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents from the MOA incorporated in the Contracts are:

Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005,

DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004.

In the execution of the regulatory program, the RU will consider not only the approaches and practices of DOE but also the regulatory principles and concepts of the Nuclear Regulatory Commission (NRC). The Policy states that

"It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities, Consolidation Information Center, Room 101L, 100 Sprout Road, Room 130 West, 101L Richland, Washington, 99352.

Guidance for the Review of TWRS Privatization Contractor Initial Safety Assessment Submittal Package

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1. INTRODUCTION

Under Contract, each TWRS Privatization Contractor is required to submit an Initial Safety Assessment (ISA) for review and approval. The Department of Energy (DOE) Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors [a.k.a., the Regulatory Unit (RU)] is required to review and evaluate the submittal. As described in the *Regulatory Policy*:

“The purpose of this review shall be to assess the viability and sufficiency of the contractor’s approaches to achieve and maintain adequate safety through its proposed design and management practices. The results of this review shall be made available for DOE consideration in contractor selection to demonstrate tank waste treatment services at fixed unit prices.”¹

A review team consisting of qualified personnel is to review the ISA and issue an Initial Safety Evaluation (ISE) Report to the Regulatory Official. The evaluation will be an objective, unbiased assessment of the Contractor’s information based on the criteria in this guidance document (Guide). The evaluation will focus on the purpose identified in the *Regulatory Process*. Specifically:

“The purpose of the Initial Safety Evaluation regulatory action is to assess the capability of the Contractor’s waste processing approach to achieve subsequent authorization for construction, operation and deactivation.”²

To establish an adequate understanding of the ISA requirements, the Review Team should become familiar with the information identified in the Guide. To understand the type of review needed and the context for each review guidance section, the Reviewers will be familiar with the entire Guide before initiating this review.

Sections 1 and 2 provide the introduction and purpose of the review guidance. Section 0 describes the overall review approach to be used in reviewing the ISA submittal package. Section 4 discusses required Contractor input (Submittal Requirements) and the Evaluation Criteria, which provides the basis for the ISE. Section 5 describes the Acceptability Review. Section 6 provides specific guidance for the Detailed Review of the ISA submittal package and identifies Review Considerations³ related to each of the Evaluation Criteria that the RU considers important regarding the substance of the Contractor’s ISA submittal package. The Review Considerations presented in Section 6 indicate the types of information that would be useful in assessing the capability of the Contractors’ waste processing approaches to achieve subsequent authorizations or in developing a perspective on the regulatory risks associated with the waste processing approaches. They are not requirements and should only be applied to the extent that they support the assessment against the Evaluation Criteria. Section 7 provides guidance toward evaluating the ISA and in identifying “open issues.”⁴

The Review Guidance draws on language found in the Contract and in Draft Rules, DOE Directives, and NRC publications in formulating some of the “Review Considerations.” The RU does not advocate a preference between DOE and NRC sources. The preferred approach is one that the Contractor adopts which is tailored to its waste processing approach and which meets the intent of the Contract. For this reason, this Guide provides alternative references when utilizing material drawn from outside the

¹*Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors*, DOE/RL-96-25, July 3, 1996, (*Regulatory Policy*), Section 6, p.4, item 4.

²*DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003 (*Regulatory Process*), Section 3.3.2, p.5.

³“Review Considerations” are not Contract requirements, but are RU-generated elaborations on the contractual Evaluation Criteria.

⁴As described in section 3.3.2 on p.6 of the *Regulatory Process*, “Insufficient information either in scope or depth to facilitate the initial safety evaluation may result in open issues that will be noted in the ISER.”

Contract. The alternative references are intended to give examples of the general nature of information appropriate for the ISA.

2. PURPOSE

The Guide incorporates the requirements for submittal and evaluation in the regulatory documents,⁵ which are part of the Contract. This Guide establishes the approach and basis that the RU will use to review the Contractor's ISA submittal package and to develop the ISE Report.

3. ISA REVIEW APPROACH

The review consists of two steps. First, an Acceptability Review is performed. This is a short duration (1-week) review to determine if the ISA submittal package is acceptable for Detailed Review by the RU (see Section 5).

If the submittal package is found acceptable, the Detailed Review (Section 6) is then performed over the balance of a 9-week period culminating in a draft RU Initial Safety Evaluation Report (ISER). "Insufficient information either in scope or depth may result in open issues that will be noted in the ISER."⁶ It is likely that there will be some open issues at the stage of design associated with the completion of Part A activities. However, open issues that are of a type that should have been resolved during Part A or that have a significant effect on the assurance of safety should be reflected in the ISE conclusions.

4. SUBMITTAL REQUIREMENTS AND EVALUATION CRITERIA

The *Regulatory Process* provides the Submittal Requirements and Evaluation Criteria for the ISA.⁷ The Submittal Requirements are the basis for assessing the completeness of the Contractors input during the RU's Acceptability Review (Section 5). In addition, the Evaluation Criteria are used to assess the adequacy of the submittal. Section 5 lists both the Submittal Requirements and the Evaluation Criteria as they are used for completeness and adequacy criteria. The Evaluation Criteria are also used in the Detailed Review (Section 6), with each subsection of Section 6 addressing a specific criterion.

5. ISA ACCEPTABILITY REVIEW

This Guide uses the term "Acceptability Review" to describe the review of the ISA for acceptability as a technical package for detailed review and evaluation. In performing the ISA Acceptability Review, the Reviewers will determine if the material satisfies the Submittal Requirements established by the Contract (completeness) and whether the Contract Evaluation Criteria are addressed in sufficient detail for a technical evaluation to be made (adequacy).

Based upon the Review Team recommendation, the RU Director will decide whether to accept the package for detailed review or to reject the package. If the package is rejected, the Regulatory Official will list the reasons for the rejection and the necessary corrective actions.⁸ (*Note: DOE/RL-96-0003 assumes the SRD and the ISMP will be approved at the time the ISA is submitted. This is not the case, and reviewers will*

⁵ *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005; *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003; *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006; and *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004.

⁶ *Regulatory Process*, p. 6.

⁷ *Ibid.* pp. 5, 6, 13, and 14

⁸ *Ibid.*, p. 15

work from the available documents. Where requirements are directly quoted, “approved” is still used in the text.)

5.1 Completeness Requirements

The ISA “submittal package shall consist of the following documentation:

- 1) Description of the design developed during part A and proposed facility operations;
- 2) Description of the Contractor’s site and its location within the Hanford Site;
- 3) An assessment of compliance to the approved SRD and the ISMP;
- 4) Description of hazards, including process hazards, and hazard controls implemented in the design and operation;
- 5) Analysis of potential design basis events;
- 6) Preliminary safety criteria against which the consequences of the potential design-basis events are compared for acceptability;
- 7) Description of potential design basis events;
- 8) Analysis of potential design basis events;
- 9) Preliminary safety criteria against which the consequences of the potential design-basis events are compared for acceptability;
- 10) Descriptions of structures, systems, and components designated as important-to-safety and the rationale for their selection;
- 11) The Contractor’s evaluations of constructability, operability, reliability, availability, maintainability, and inspectability;
- 12) An Initial Safety Analysis Report that
 - a) Defines the projected safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, components with prescribed safety functions, operating modes, operating conditions, representative off-normal internal events, representative external events, representative safety analyses and results, including major uncertainties in data and analyses;
 - b) Describes how the facility should perform such that the radiological, nuclear, and process safety standards and requirements in the SRD and in applicable regulations are met; and
 - c) Describes how adequate protection of the public, the workers, and the environment should be achieved;
- 15) Draft deactivation plan; and
- 16) Outlines of the:
 - a) Construction Authorization Request; [LMAES only]
 - b) Operating Authorization Request; [LMAES only]
 - c) Emergency Response Plan;
 - d) Unreviewed Safety Question Plan;
 - e) Conduct of Operations Plan;
 - f) Technical Safety Requirements;
 - g) Training and Qualification Plan;
 - h) Maintenance Implementation Plan;

- i) Occurrence Reporting Procedures;
- j) Environmental Radiological Protection Program;
- k) Radiation Protection Program;
- l) Operational Analysis and Assessment Reports;
- m) Deactivation Safety Assessment; and [LMAES only]
- n) Deactivation Authorization Request.”⁹ [LMAES only]

5.2 Adequacy Requirements

“The Contractor shall [also] submit any other information [beyond that specifically required for the ISA submittal] that could materially affect this [Initial Safety] [E]valuation by the Director of the Regulatory Unit.”¹⁰ This includes information on the following Evaluation Criteria which “the Initial Safety Evaluation will address:

- 1) The degree to which the Contractor’s proposed safety-related activities are being performed in compliance with the approved SRD;
- 2) The degree to which the Contractor’s proposed safety-related activities are being performed in compliance with the approved ISMP;
- 3) The adequacy with which the hazards, including process hazards, attendant to the Contractor’s proposed activities have been assessed and controlled;
- 4) The adequacy of the selection and definition of design basis events for the proposed facilities;
- 5) The acceptability of the results of analysis of representative design basis events;
- 6) The adequacy of the categorization of systems, structures, and components that are important to safety;
- 7) Adequacy of the projected safety basis for the facility and its operation;
- 8) The adequacy of the outlines of various plans, programs, and requests that will be generated and implemented in Part B;
- 9) The confidence associated with safety-related aspects of constructability, operability, reliability, availability, maintainability, and inspectability;
- 10) The resolvability of open issues, and
- 11) The adequacy of the draft deactivation plan.”¹¹

The Review Team should judge the acceptability of the submittal based upon the completeness requirements described in Section 5.1 and the adequacy requirements described in Section 5.2. In making this determination, the Review Team may need to refer to the corresponding sections of the Detailed Review (Section 6) to obtain additional information needed to complete the adequacy assessment. While a detailed review is not expected during the one week allocated for the Acceptability Review, a top-level review of the technical content of the submittal against information in Section 6 is recommended.

⁹ *Regulatory Process*, pp. 13-14.

¹⁰ *Ibid.* p. 14.

¹¹ *Ibid.*, pp. 5 - 6.

6. ISA DETAILED REVIEW

This Section uses Evaluation Criteria, Review Intent statements, and Review Considerations to guide the Reviewers. To clarify:

1. Evaluation Criteria are contract requirements and must be used to assess the Contractor's submittal.
2. Review Intent statements elaborate on the Evaluation Criteria and provide more specific descriptions and examples of the judgments that may be used by the Reviewers in conducting the detailed review.
3. Review Considerations are lines of inquiry used in assessing the submittal package against the Evaluation Criteria.

The Reviewers are encouraged to use Review Considerations to assist the review but should not apply them as Criteria. Many Review Considerations involve current and future expectations. The Reviewers may augment the Review Considerations with other lines of inquiry drawn from personal expertise.

Review Considerations were developed from a variety of sources, including:

- SRD¹² or ISMP¹³ review guidance;
- Top-Level Safety Standards and Principles; and,
- Other sources, such as related DOE Directives¹⁴ or NRC documentation.¹⁵

In general, Review Considerations were developed from documents that relate to Contractor activities extending into subsequent authorizations for construction, operation, and deactivation. The use of such documents in the development of the ISA Review Considerations provides a useful reference in assessing the Contractors capability to complete future authorizations. This enhances the accuracy of the assessments made in the ISE.

This Guide uses the term “should” to identify Contract requirements that the Reviewers must verify have been met. This Guide uses the term “will” when the reviewers are required to assess the Contractor's capability to achieve subsequent authorizations or to determine the regulatory risks associated with the Contractor's firm-fixed-price proposal. The term “may” is used to identify other useful but less significant avenues of inquiry. The Reviewers are expected to address all of the “should” and “will” elements during this review and, based on their expertise, address the “may” elements they deem useful.

As part of the Detailed Review, the Reviewers will prepare detailed questions to request Contractor response.¹⁶ In forming detailed evaluation conclusions, the Reviewers will assess the quality, depth, breadth, and responsiveness of the Contractor's submittal.

¹²Guidance for the Review of TWRS Privatization Contractor Safety Requirements Document Submittal Package, RL/REG-97-08, June 1997. (SRD Review Guidance)

¹³Guidance for the Review of TWRS Privatization Contractor Integrated Safety Management Plan Submittal Package, RL/REG-97-07, June 1997. (ISMP Review Guidance)

¹⁴Such as many of the DOE Orders and Standards already cited. Review Considerations have been developed from DOE directives that were superseded by new directives, when the older directives provided more useful review guidance. One of the main reasons for developing the new DOE directives was to remove material that was more suitable for guidance or input to the work smart standards process. The new DOE directives did not differ in principle from those that they superseded and the material from the superseded DOE directives is being used in Review Considerations, which are guidance rather than requirements. Thus, the superseded DOE directives are an appropriate source for Review Considerations.

¹⁵Such as, USNRC Standard Review Plan For The Review of a License Application for a Fuel Cycle Facility, Draft NUREG 1520, February 15, 1995; R. Milstein, *Integrated Safety Analysis Guidance Document*, USNRC/NMSS, Draft NUREG 1513, undated; USNRC Regulatory Guide 3.52, *Standard Format and Content for the Health and Safety Sections of License Applications for Fuel Cycle Facilities*, Revision 2 (DRAFT), January 1995.

6.1 Design, Operations, and Site Description

Evaluation Criterion

The descriptions of design, operations, and siting have no specific ISA Evaluation Criteria in the Contract. However, sufficient information should be provided by the Contractor to enable the review of all Evaluation Criteria cited in the Guide.

Review Intent

The intent of this section is to:

- a) Determine if there are significant departures from the design principles in the Top-Level Safety Standards and Principles;
- b) Verify that process and facility descriptions are provided and are comparable with the hazards assessment, the selection and analysis of design-basis events, and the identification of important-to-safety SSCs;
- c) Verify that the location of the classes of radiological receptors (worker, co-located worker, and public) can be clearly identified;
- d) Verify that adequate meteorological and seismic information is provided and is consistent with that employed in the analysis of design-basis events;
- e) Verify that any safety-related interfaces between the Contractor's site and the remainder of the Hanford Site have been identified (e.g., utilities, emergency response); and
- f) Verify that the documents used as a basis for the natural and man-made external events can be identified.

Review Considerations

6.1.1 General Design Considerations

The Reviewers will assess the consistency between the design and the following Top-Level Safety Standards and Principles.

Safety Design¹⁷

"The facility should be designed for a set of events such as: normal operation, including anticipated operational occurrences, maintenance, and testing; external events; and postulated accidents."

Defense in Depth¹⁸

"To compensate for potential human and mechanical failures, a defense-in-depth strategy should be applied to the facility commensurate with the hazards such that assured safety is vested in multiple, independent safety provisions, no one of which is to be relied upon excessively to protect the public, the workers, or the environment. This strategy should be applied to the design and operation of the facility."

¹⁶Regulatory Process, Section 4.2.1, p.14.

¹⁷Top-Level Safety Standards and Principles, Section 4.2.1.1, p.8.

¹⁸Ibid., Section 4.1.1, p.6.

Proven Engineering Practices¹⁹

“Safety technologies incorporated into the facility design should have been proven by experience or testing and should be reflected in approved codes and standards. Significant new design features should be introduced only after thorough research and model or prototype testing at the component, system, or facility level, as appropriate.”

Mitigation²⁰

“The facility should be designed to retain the radioactive material through a conservatively designed confinement system for the entire range of events considered in the design basis. The confinement system should protect the workplace and the environment.”

Safety Margin Enhancement²¹

“Design features that enhance the margins of safety through simplified, inherent, passive, or other highly reliable means to accomplish safety functions should be employed to the maximum extent practical.”

Radiation Protection Features²²

“At the design stage, radiation protection features should be incorporated to protect workers from radiation exposure and to keep emissions of radioactive effluents ALARA and within prescribed limits.”

Nuclear Criticality Safety²³

“The facility should be designed and operated in a manner that prevents nuclear criticality.”

Deactivation, Decontamination, and Decommissioning Design²⁴

“The design of the facility should incorporate provisions to facilitate deactivation and the final decommissioning. The objective of these provisions should be to reduce radiation exposures to Hanford Site personnel and the public both during and following deactivation and decommissioning activities and to minimize the quantity of radioactive waste generated during deactivation, decontamination and decommissioning.”

Automatic Systems²⁵

“Automatic systems should be provided that would place and maintain the facility in a safe state and limit the potential spread of radioactive materials when operating conditions exceed predetermined safety setpoints.”

¹⁹ *Top-Level Safety Standards and Principles*, Section 4.2.2.1, p.9.

²⁰ *Ibid.*, Section 4.1.1.4, p.6.

²¹ *Ibid.*, Section 4.2.5.1, p.10.

²² *Ibid.*, Section 4.2.3.2, p.9.

²³ *Ibid.*, Section 4.2.2.5, p.9.

²⁴ *Ibid.*, Section 4.2.3.3, p.10.

²⁵ *Ibid.*, Section 4.1.1.5, p.6.

Common-Mode/Common-Cause Failure Mitigation²⁶

“Design provisions should be included to limit the loss-of-safety functions due to damage to several structures, systems, or components important-to-safety resulting from a common-cause or common-mode failure.”

Safety System Design and Qualification²⁷

“Structures, systems, and components important-to-safety should be designed and qualified to function as intended in the environments associated with the events for which they are intended to respond. The effects of aging on normal and abnormal functioning should be considered in design and qualification.”

Human Error²⁸

“The possibility of human error in facility operations should be taken into account in the design by facilitating correct decisions by operators and inhibiting wrong decisions and by providing means for detecting and correcting or compensating for error.”

Instrumentation and Control Design²⁹

“Sufficient instrumentation and control capability should be provided so that under normal operating and postulated accident conditions the operators can diagnose facility conditions, place and maintain the facility in a safe state, and mitigate accidents. If necessary, measures should be provided to protect the operator in the performance of these functions.”

6.1.2 Design Description

6.1.2.1 Facility Description

Review Consideration 1 - Facility Description³⁰

The Contractor’s description of the facility may include the purpose and function of each building, design information regarding the facility’s resistance to the effects of external events, location and arrangement of the buildings on the site and their distance from the facility fence and the site boundary, and other features that could affect hazards identification, hazards characterization, and risk- informed decision making to control the hazards.

6.1.2.2 Systems Description

Review Consideration 1 - Systems Description³¹

The Reviewers may confirm for major safety-related systems that the Contractor’s descriptions include the basic functions of the systems, the key components/equipment involved (e.g., sizes, inventories, etc.), and approximate operating ranges and limits (e.g., pressures, temperatures, processed material states, flow rates, etc.). These descriptions should support hazards identification, hazards characterization, and risk-informed decision making to control the hazards.

²⁶ *Top-Level Safety Standards and Principles*, Section 4.2.2.2, p.9.

²⁷ *Ibid.*, Section 4.2.2.3, p.9.

²⁸ *Ibid.*, Section 4.2.6.1, p.10.

²⁹ *Ibid.*, Section 4.2.6.2, p.10.

³⁰ *SRD Review Guidance*, Section 8.1, Attributes 2 and 3, p.22.

³¹ *Ibid.*, Attribute 2, p.22.

Review Consideration 2 - Process Design and Equipment³²

The Reviewers may verify for major safety-related systems that the Contractor's submittal includes information on process design, materials of construction, piping and instrumentation diagrams (P&IDs), electrical classification, relief system design and design-basis, ventilation system design, design codes and standards employed, material and energy balances, and safety systems (e.g., interlocks, detection, and suppression systems). The information is expected to confirm that the equipment is appropriate for the operation, that its integrity is maintained, and that it meets appropriate codes and standards.

6.1.2.3 Process Description

Review Consideration 1 - Process Description³³

The Reviewers may confirm that the Contractor's descriptions of its planned tank waste treatment processes include the basic functions and theories of each process in sufficient detail to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards.

Review Consideration 2 - Process Flow Diagrams

The Reviewers may confirm for primary processes that annotated process flow diagrams are provided which schematically describe the general piping and tankage interconnections for all key processing subsystems along with summary information on tank volumes, state parameters (pressure, temperature, density, etc.), and processing times at various locations, along with nominal flow-rates as appropriate. Information is expected to be consistent with that reflected in Review Considerations 3 and 4, below and may in part be referenced to that submittal material.

Review Consideration 3 - Major Components - Function and Operation³⁴

The Reviewers may verify for major safety-related components that the Contractor's submittal includes the general arrangement, function, and operation of major components in the process. It should include process schematics showing the major components and instrumentation and, if appropriate, chemical flowsheets showing compositions of the various process streams. The submittal should also include maximum intended inventory, and safe upper and lower limits for such items as temperatures, pressures, flows, and compositions.

Review Consideration 4 - Process Operating Ranges and Limits³⁵

The Reviewers may verify the consistency between the operating ranges and limits for all measured variables (e.g., temperatures, pressures, flows, and compositions) used in engineered or administrative controls to ensure safe operation of the process and the values assumed in the ISA.

6.1.3 Operations Description

Review Consideration 1 - Operational Modes

The Reviewers may determine whether operational modes described provide an adequate basis to understand the source of risks related to the modes of operation, including such activities as:

³²Draft NUREG 1520, Section 4.5.3, item 4c, p.4.0-8.

³³*SRD Review Guidance*, Section 8.1, Attribute 1, p.22.

³⁴Draft NUREG 1520, Section 4.5.3, item 4b, p.4.0-8.

³⁵*Ibid.*, Section 4.5.3, item 4d, p.4.0-8.

- Startup
- Hot and Cold Testing
- Normal Operations
- Maintenance
- Shutdown

Review Consideration 2 - Operational Risks

For each operational mode, the Reviewers may spot-check to determine whether the Contractor has identified operational characteristics related to safety. The Reviewers will assess whether hazards and risks associated with each operational mode are described and whether protective measures have been identified for each.

For example, the Reviewers would assess whether high radiation-field maintenance operations are conducted in a contact mode or remotely in shielded cells and whether RESW limits are met.

6.1.4 Site Description

Some aspects of the site description are likely to be included in the Contractor's environmental submittals required by the Contract. As such, it is acceptable for the Contractor to reference these documents in the ISA Submittal.

Review Consideration 1 - Site Description³⁶

The Reviewers may verify that the Contractor's description of the site includes, as appropriate, the site geography, demography, meteorology, hydrology, geology, and seismology, sufficient to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards. Man-made external events that contribute to the hazards to the facility workers or could contribute to the "release" of the hazards associated with the facility should be included. If information from sources at the Hanford Site is used, the Contractor should reference it and provide its pedigree. The characteristics of the external events may be described as well.

Review Consideration 2 - Geography³⁷

The Reviewers may verify that the Contractor has provided a brief description of the site geography, including its location relative to prominent natural and man-made features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, etc.

Review Consideration 3 - Demography³⁸

The Reviewers may verify that the Contractor has provided population information based on recent census data to show population distribution as a function of distance from the facility. This includes descriptions, distances, and directions to nearby public facilities (e.g., schools, hospitals, parks, etc.) and nearby industrial areas that may introduce potential hazards, and uses of land in the area of concern (i.e., residential, industrial, commercial, agricultural).

Review Consideration 4 - Meteorology³⁹

The Reviewers may verify that the Contractor has provided frequency distribution for wind speed and wind direction. The annual amount of precipitation should be given. Type, frequency, and magnitude of

³⁶ *SRD Review Guidance*, Section 8.1, Attribute 4, p.23.

³⁷ Draft NUREG 1520, Section 1.3.3, p.1.3-2.

³⁸ *Ibid.*, Section 1.3.3, p.1.3-2.

³⁹ *Ibid.*, p.1.3-3.

severe weather (e.g., tornado, hurricane, etc.) should be described. The Reviewers will verify that the information provided is consistent with that employed in the analysis of design- basis events.

Review Consideration 5 - Hydrology⁴⁰

The Reviewers may verify that the Contractor has provided characteristics of nearby rivers, streams, and bodies of water as appropriate. Distance to the water table should be provided. Groundwater flow for the site should be described. The submittal should contain an evaluation for a 100-year flood.

Review Consideration 6 - Geology⁴¹

The Reviewers may verify that the Contractor has provided the geological information necessary to understand any regional geological phenomena of concern for facility operation, including geologic history, soil structures, and other aspects of the geologic character of the site. The Reviewers may evaluate the nature of investigations performed and the results of the investigations.

Review Consideration 7 - Seismicity

The Reviewers may verify that the Contractor has provided information on the seismic history of the site. Maximum vertical and horizontal accelerations should be presented, along with the return period of the events. The Reviewers may verify that the information provided is consistent with that employed in the analysis of design-basis events.

Review Consideration 8 - External Events

The Reviewers may verify that the Contractor has provided a discussion of natural phenomena (e.g., tornadoes, hurricanes, earthquakes) and other external events that could have an adverse impact on safety. The discussion may indicate which events are considered to be incredible and the basis for that determination.

6.2 SRD and ISMP Compliance

The SRD and ISMP are expected to be revised as the facility progresses toward operation. At any fixed point in time, the Contractor is expected to comply with the current versions of the SRD and the ISMP.

Evaluation Criteria⁴²

“The degree to which the Contractor's proposed safety-related activities are being performed or can be performed in compliance with the approved SRD; and

The degree to which the Contractor's proposed safety-related activities are being performed or can be performed in compliance with the approved ISMP.”

Review Intent

The Reviewers will assess the Contractor's compliance with the SRD and ISMP by evaluating commitments made in these documents. The Reviewers will place emphasis on the assurance of adequacy, safety of the design, and compliance with design safety standards.

⁴⁰ Draft NUREG 1520, Section 1.3.3, p.1.3-4.

⁴¹ DOE Standard Preparation Guide for U. S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports, DOE-STD-3009-94, July 1994, Section 1.4.3, p.26.

⁴² *Regulatory Process*, Section 3.3.2, p.5-6.

Review Considerations

6.2.1 Compliance with the SRD

Review Consideration 1 - Preliminary Implementation

The Reviewers will evaluate contractually-binding provisions embodied in the SRD and the Contractor's progress in implementing all detailed programs.

Review Consideration 2 - Design Features

On a sampling basis, the Reviewers will evaluate safety-related activities to verify consistency with design requirements of the SRD.

6.2.2 Compliance with the ISMP

Review Consideration 1 - Preliminary Implementation

The Reviewers will confirm that the Contractor is implementing the commitments and the programs described in the ISMP at the stage of the ISA submittal package. The Contractor may reference schedules and milestones that describe the plans for increasing the level of implementation during Part B. The purpose of reviewing these particular items is to assess the consistency between program implementation and design maturity.

Review Consideration 2 -Safety-Related Activities

The Reviewers will assess the Contractor's compliance with the safety-related activities described in the ISMP.

6.3 Hazards Assessment and Control

The Contractor's Hazards Assessment Report (HAR) is also expected to be revised as the facility progresses toward operation. The HAR will become more detailed and specific as the design progresses. It is possible that the HAR will have been revised following its submittal with the SRD. If so, this increase in detail of the HAR should be reflected in the ISA.

Evaluation Criterion⁴³

"The adequacy with which the hazards, including process hazards, attendant to the Contractor's proposed activities have been assessed and controlled."

Review Intent

The Reviewers will assess the adequacy of the revisions, if any, that the Contractors have made to the HAR by:

- a? Evaluating the adequacy of the identification and evaluation of the hazards including process hazards, and the adequacy of the control recommendations; and
- b? Identifying areas in which implementation of the hazards control measures would be technically challenging or require innovative technologies for the following review considerations associated with the Top-Level Standards.

⁴³Regulatory Process, Section 3.3.2, item 3, p.6.

Review Considerations

Review Consideration 1 - Description of Accident Sequences⁴⁴

The Reviewers will assess the accident progressions that link initiating events with preventive and mitigation events and other contributing phenomena, noting each response, action, or indication required to initiate action that is relevant to the accident sequence progression. The Reviewers will assess the adequacy of the Contractor's rationale for binning the design-basis event in a broad frequency range. The Reviewers will assess the adequacy of the facility and equipment response to the loads postulated to be present during natural phenomena.

The Reviewers will assess the Contractor's evaluation of secondary events directly caused by natural phenomena, such as earthquake-induced fires, based on their physical possibility for facility conditions (i.e., the induced accident must already exist in the absence of the seismic event).

Review Consideration 2- Hazards Analysis

The Reviewers will determine if the Contractor has a process for periodically updating the hazards analysis. The Reviewer will determine the quality of the update by assessing the Contractor's sources of data and its traceability. The top-level radiological and nuclear safety standards for workers, co-located workers and the public for various situations are listed in Table 1 of DOE/RL-96-0006. Footnotes to the table refer to the origin of a specific standard.

Updated Hazards Assessment⁴⁵

"The Contractor should review and update the hazards analysis periodically to assure that the process hazards analysis is consistent with the current process.

Hazards Control - Operations Risk Goal⁴⁶

"The risk, to the population (public and workers) in the area of the Contractor's facility, of cancer fatalities that might result from facility operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks to which members of the U.S. population generally are exposed".⁴⁷

Hazards Control - Accident Risk Goal⁴⁸

"The *risk*, to an average individual in the vicinity of the Contractor's facility, of prompt fatalities that might result from an accident *should* not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population generally are exposed."⁴⁹

Hazards Control - Worker Accident Risk Goal⁵⁰

"The risk, to workers in the vicinity of the Contractor's facility, of fatality from radiological exposure that might result from an accident should not be a significant contributor to the overall occupational risk of fatality to workers."⁵¹

⁴⁴ DOE-STD-3009-94, Section 3.4.2.X.1: "Scenario Development," pp. 56-57.

⁴⁵ *Top-Level Safety Standards and Principles*, Section 5.2.2, p.15.

⁴⁶ *Ibid.*, Section 3.1.1, p. 4.

⁴⁷ For evaluation purposes, individuals are assumed to be located within 10 miles of the controlled area.

⁴⁸ *Top-Level Safety Standards and Principles*, Section 3.1.2, p.4.

⁴⁹ For evaluation purposes, individuals are assumed to be located within one mile of the controlled area.

⁵⁰ *Top-Level Safety Standards and Principles*, Section 3.1.3, p.4.

⁵¹ For evaluation purposes, workers are assumed to be located within the controlled area.

Hazards Control - Radiological and Nuclear Safety Standards⁵²

“The top-level radiological and nuclear safety standards for workers, co-located workers, and the public for various situations are listed in Table 1 [found in DOE/RL-96-0006, page 2]. Footnotes to the table refer to the origin of a specific standard. Additional information on terminology, definitions, and methods can be found in those references. As noted in the references, some of the standards can not be applied independent of other dose contributors located on the Hanford Site.”

Hazards Control - Radiation Protection Objective⁵³

“Ensure that during normal operation radiation exposure within the facility and radiation exposure and environmental impact due to any release of radioactive material from the facility is kept as low as is reasonably achievable (ALARA) and within prescribed limits, and ensure mitigation of the extent of radiation exposure and environmental impact due to accidents.”

Hazards Control - Public Protection⁵⁴

“Measures in the design and operation of the facility to protect the public against accident conditions should be evaluated against acceptable guidelines to demonstrate that they perform their intended purpose with high confidence.”

Hazards Control - Worker Protection⁵⁵

“Measures in the design and operation of the facility to protect the workers against accident conditions should be evaluated using an acceptable approach to demonstrate that they perform their intended purpose with high confidence.”

Hazards Control - Accident Vulnerability Mitigation⁵⁶

“Particular care should be taken to identify, evaluate, and prevent and/or mitigate any vulnerabilities to accidents that might, by themselves, result in a release of radioactive material that exceeds acceptable levels.”

6.4 Selection of Design-Basis Events

Evaluation Criteria

“The adequacy of the selection and definition of design-basis events for the proposed facilities.”⁵⁷

Review Intent

The intent of this section is that the Reviewers perform the following:

- a? Identify and evaluate the method for design-basis event definition and selection;

⁵² *Top-Level Safety Standards and Principles*, Sections 2 and 3, pp. 2-5.

⁵³ *Ibid.*, Section 3.2, p.4.

⁵⁴ *Ibid.*, Section 3.3.1, p.4.

⁵⁵ *Ibid.*, Section 3.3.2, p.4.

⁵⁶ *Ibid.*, Section 3.3.3, p.5.

⁵⁷ *Regulatory Process*, Section 3.3.2, item 4, p.6.

- b? Assess if the set of events adequately bounds the range of consequences and challenges to the important-to-safety SSCs from credible accidents and abnormal events; and
- c? Assess design-basis events for identifying or evaluating effectiveness of controls and for establishing design requirements for SSCs important-to-safety.

Review Considerations

Review Consideration 1 - Initiating Conditions

The Reviewers will determine if the Contractor has identified the appropriate initiating conditions for the design-basis events. Table 1.3 from the *AICHE Guidelines* provides a list of possible initiating events, propagating events, risk reduction factors (controls), and incident outcomes. The initiating events can originate from process upsets, management system failures, human errors, and external events (e.g., high winds, floods). Propagating events include equipment failure, ignition sources, management system failure, human error, domino effects (other containment failures or material releases), and external conditions. Risk reduction factors include control/operator responses, safety system responses, mitigation system responses, and emergency plan responses, etc. Incident outcomes include information not related to initiating conditions.

Review Consideration 2 - Compliance with the Safety Analysis Standards in the SRD

The Contractor's SRD is to contain standards addressing the manner in which safety analyses will be conducted.⁵⁸ The Reviewers will identify these standards and verify that the potential design-basis events described and the method for their definition and selection complies with the applicable SRD requirements addressing the performance of safety analyses.

Review Consideration 3 - Design-Basis Events for Worker Protection

Table 1 of the *Top-level Safety Standards and Principles*⁵⁹ requires that the Contractor propose dose standards for workers for unlikely and extremely unlikely events. The proposed dose standards should be reflected in the selection of design basis events for worker protection.

Review Consideration 4 - Design-Basis Operational Events.

The selection of design-basis operational events provides a means to reduce the information developed in the hazard assessment to a manageable set of events to be used for the remainder of the accident analysis. In order for the accident analysis to serve its purpose, this set must be selected in a way that does not discard any important information from the hazard assessment. In particular, the set of operational events should represent the accident release mechanisms identified in the hazard assessment. Typically these representative events should include fires, spills, process disturbances, explosions, and criticality events.⁶⁰

Design Criteria for Structures, Systems, and Components

As indicated in the *Regulatory Process*, the design-basis events are developed and analyzed to establish

“... the performance requirements of structures, systems, and components that are necessary to: 1) ensure the integrity of the safety boundaries protecting the worker; 2) place and maintain the facility in a safe state indefinitely; or 3)

⁵⁸ *Top-Level Safety Standards and Principles*, Section 4.2.1.3, defines the manner in which safety analyses should be conducted. Subordinate standards for safety analysis which stem from this part of the Contract become requirements once approved as part of the SRD.

⁵⁹ *Ibid.*, Sections 2 and 3, pp. 2-5.

⁶⁰ *Nuclear Safety Analysis Reports*, Section 4.1.2.

prevent or mitigate the event consequences so that the radiological exposures to the general public or the workers would not exceed appropriate limits.”⁶¹

The Reviewers will evaluate the design-basis events in the ISA and the method for identification and selection of design-basis operational events to determine whether the design-basis events would be effective for establishing a range of design parameters for SSCs required to perform the stated safety functions.

Compliance with the Radiological and Nuclear Safety Standards

Where the selection and analysis of design-basis operational events is used to demonstrate compliance with the radiological and nuclear safety standards in the approved Safety Requirements Document (SRD), the Reviewers may examine on a sampling basis the method employed for selecting the design-basis operational events of each type for each receptor group and probability category to verify that it will result in a set of design-basis events that bound the consequences, in terms of dose expected from any other accident in their receptor group and probability category. As a part of this review, the Reviewers will evaluate on a sampling basis any justification provided by the Contractor to demonstrate that the design-basis operational events are bounding. Finally, the Reviewers will examine the resultant set of operational events themselves to confirm they do, in fact, include postulated events that are bounding upon the receptor groups and probability categories.

Review Consideration 5 - Design-Basis Natural and Man-made External Events

To obtain construction authorization, the “Contractor’s design [must] properly account[s] for the natural and man-made external events associated with the designated site.”⁶² This is demonstrated, in part, through the selection and analysis of design-basis natural phenomena and external events.⁶³ The Reviewers will review the selection and definition of design-basis natural and man-made external events in the ISA to assess the capability of the Contractor’s waste processing operation to achieve subsequent authorization for construction. The Reviewers may consider employing the method described below to perform this review.

There are two fundamentally different approaches that have traditionally been accepted for this demonstration. The first of these has been accepted for the safety analyses of existing DOE facilities. It evaluates both the response of SSCs and radiological consequences. This approach is to develop design-basis natural and man-made external events of each type (e.g., seismic event, aircraft crash, extreme wind, and tornado) that bound the corresponding events in each of the probability categories for which human dose standards have been established (e.g., in the SRD: anticipated events, unlikely events, and extremely unlikely events).⁶⁴ The response of the facility structures, systems, and components (SSCs) to these postulated events is then analyzed and the event consequences to the various receptor groups (e.g., workers, co-located workers, and the public) are compared to the established dose standards to demonstrate compliance. This approach is discussed in DOE-STD-3009-94.⁶⁵

A second approach to demonstrating compliance with human dose standards that has been accepted for the safety analysis of the design of new facilities relies on the preservation of the SSCs’ intended safety

⁶¹ *Regulatory Process*, Glossary, p.31.

⁶² *Ibid.*, Section 3.3.3, item 4, p.6.

⁶³ Design-basis events are “Postulated events providing bounding conditions for establishing the performance requirements of structures, systems, and components that are necessary to: 1) ensure the integrity of the safety boundaries protecting the worker; 2) place and maintain the facility in a safe state indefinitely; or 3) prevent or mitigate the event consequences so that the radiological exposures to the general public or workers would not exceed appropriate limits. The Design-Basis Events also establish the performance requirements of the structures, systems, and components whose failure under Design-Basis Event conditions could adversely affect any of the above functions.” DOE/RL-96-0003, Glossary, p.31.

⁶⁴ *Top-Level Safety Standards and Principles*, Table 1.

⁶⁵ DOE-STD-3009-94, Sections 1.5 - 1.7 and Chapter 3

functions for design-basis operational events where the SSCs are or have been exposed to design-basis external events. This is acceptable if the sources of radiological and nuclear exposures are limited to operational events. This approach is to develop design-basis natural and man-made external events of each type that bound all corresponding events that have likelihoods greater than or equal to those in the extremely unlikely event category.⁶⁶ The challenges that these design-basis events pose to the SSCs of the facility (e.g., seismic loads from specific peak ground accelerations, wind loadings, hydrological loadings, and missile impacts) are then determined from the analysis of the postulated events. These challenges are then incorporated into the applicable design specifications for SSCs important-to-safety to ensure that these SSCs will withstand the design-basis natural and man-made external events, thereby ensuring that the SSCs retain their intended safety functions and continue to assure that established dose standards will be met for all design-basis operational events.⁶⁷ This is the approach employed by the NRC for nuclear power plants. It is described in NUREG-0800 and DOE Order 6430.1A.⁶⁸

If the Contractor adopts the first approach in which the response of the facility design is to be evaluated against design-basis natural and man-made external events, the Reviewers will evaluate the descriptions of the potential design-basis external events, and the method employed for their identification and selection to determine the extent to which:

- The potential design-basis natural and man-made external events described in the ISA include postulated events that bound the dose to each receptor group for the corresponding external events of each type in each of the probability categories established in Table 1 of the *Top-level Safety Standards and Principles*.⁶⁹
- The potential design-basis natural and man-made external events described in the ISA include postulated events of each type that bound the challenges to facility SSCs that are relied upon to respond to, or to mitigate, natural and man-made external events, for all corresponding natural and man-made external events that have likelihoods greater than or equal to those in the extremely unlikely event category.
- The potential design-basis man-made external events, described in the ISA address the postulated events identified and analyzed in the authorization basis of other facilities exposed to similar external conditions such as TWRS (e.g., the TWRS Basis for Interim Operation and the TWRS Flammable Gas Justification for Continued Operation).
- The potential design-basis natural external events described in the ISA incorporate the postulated events identified and analyzed in the authorization basis of other facilities exposed to similar external conditions such as TWRS that are induced by natural phenomena (e.g., seismically induced flammable gas deflagration in one or more waste tanks).

If the Contractor adopts the second approach in which design-basis natural and man-made external events are analyzed to develop design criteria for facility SSCs, the Reviewers will evaluate the descriptions of the potential design-basis external events, and the method employed for their identification and selection to determine the extent to which:

- The potential design-basis natural and man-made external events described in the ISA include postulated events of each type that bound the challenges to facility SSCs that are important-to-

⁶⁶*Top-Level Safety Standards and Principles*, Table 1, p.2.

⁶⁷Where this approach is employed, the safety analysis must also show that appropriate design provisions have been to ensure that the design-basis natural or man-made external events will not cause any SSC that is not important-to-safety to fail in a manner that will impede an important-to-safety SSC from performing its safety function. See DOE 6430.1A, Section 13.2.

⁶⁸*NRC Standard Review Plan for Commercial Light Water Nuclear Power Reactors*, NUREG-800, Chapter 3. and DOE 6430.1A, *General Design Criteria*.

⁶⁹*Top-Level Safety Standards and Principles*, Section 2 and Table 1 and Standard 4 Paragraph c.2)(c) of DE-AC06-RL13308 and DE-AC06-RL13309.

safety for all corresponding natural and man-made external events that have likelihoods greater than or equal to those in the extremely unlikely event category.

- The potential design-basis man-made external events described in the ISA address the postulated events identified and analyzed in the authorization basis of other facilities exposed to similar external conditions such as TWRS (e.g., the TWRS Basis for Interim Operation and the TWRS Flammable Gas Justification for Continued Operation).
- The potential design-basis natural external events described in the ISA incorporate the postulated events identified and analyzed in the authorization basis of other facilities exposed to similar external conditions such as TWRS that are induced by natural phenomena (e.g., seismically induced flammable gas deflagration in one or more waste tanks).

6.5 Analysis of Design-Basis Events

The results of the analysis of design-basis events consist of an identification of potential accidents, the consequences of the accidents, and the controls (i.e., the structures, systems, equipment, components, and personnel) relied on to prevent the accidents from occurring or to reduce their consequences.

Evaluation Criterion⁷⁰

“The acceptability of the results of analysis of representative design-basis events...”

Review Intent

The intent of this section is that the Reviewers:

- a? Evaluate the Contractor’s method for determining design-basis events and the acceptability of the consequences relative to the radiological dose and other applicable nuclear and process safety standards in the SRD; and
- b? Identify areas where the evaluation takes credit for control measures that will be technically challenging or require innovative technologies.

Review Considerations

Review Consideration 1 - Method of Analysis⁷¹

The Reviewers will determine whether the Contractor has summarized the methods used to quantify the consequences of operational accidents, natural phenomena events, and external events selected in Section 6.4, “Selection of Design-Basis Events.” The Contractor may identify and describe any computer programs used to implement methods discussed below. The Contractor may include in the description the origin of the code, its precedent for use, input data, the range of variables investigated, the basic analytical models, their interrelationships, and the progression of the analysis. The Contractor may briefly summarize and reference detailed information on algorithms, computational and analytical bases, and software quality assurance measures. Documentation of methodology might include the following:

- a? Methods used to estimate radiological or other hazardous material source terms for DBEs including: (1) basic approach for estimating physical facility damage from DBEs; (2) general basis for assigning material-at-risk quantities not directly derived from hazard identification, if

⁷⁰ *Regulatory Process*, Section 3.3.2, item 5, p.6.

⁷¹ DOE-STD-3009-94, Section 3.4.1, p.55.

differing values are used; and (3) basis for material release and respirable fractions or release rates used.

- b? Methods used to estimate dose and exposure profiles including assumptions on variables such as meteorological conditions, time dependent characteristics, activity, and release rates or duration for radioactive or other hazardous materials that could be released to the environment.

Review Consideration 2 - Definition of Acceptance Criteria for Consequences of Design-Basis Events

The Reviewers will verify that the Contractor has submitted the required preliminary safety acceptance criteria against which the consequences of the potential design-basis events are compared for acceptability.⁷² The Reviewers will assess whether the Contractor's preliminary acceptance criteria are reasonable, in light of the risks associated with the design-basis events.

Review Consideration 3 - Estimate of Accident Consequences

The Reviewers will verify that the Contractor, in addition to the description of the accident sequence, has provided an estimate of the consequences resulting from the accident described in the analysis. If the sequence would result in a release of radioactive material, or if a criticality would occur, the dose to the workers, co-located workers, and to the public should be estimated.⁷³ If the sequence would result in a release of toxic material, the health impact to the workers, co-located workers, and public will be estimated.

Review Consideration 4 - Controls for Design-Basis Accidents

The Reviewers will determine which controls (i.e., the structures, systems, equipment, components, and personnel) are relied on to prevent the design-basis accidents from occurring or to reduce their consequences. Design-basis event analysis may include the effects of the controls (SSCs). The Reviewers will identify any areas where the evaluation takes credit for control measures that will be technically challenging or require innovative technologies.

6.6 Adequacy of SSC Categories

Evaluation Criterion⁷⁴

“The adequacy of the categorization of systems, structures, and components that are important-to-safety”

Review Intent

The intent of this section of the review is to assess the adequacy of Contractor's categorization of systems, structures, and components that are important-to-safety by:

- a? Verifying that the preliminary design of the SSCs is consistent with the roles assigned to them in the hazards assessment and accident analysis. Verifying that important-to-safety SSCs are identified for all identified hazards and control measures that require SSCs. (Note that this part of the review supports the evaluation of the adequacy of the projected safety basis.); and

⁷² See Section 6.7 of this Guide.

⁷³ Further guidance on the calculation of consequences will be provided in the chemical safety and radiological safety chapters of Draft NUREG 1520.

⁷⁴ *Regulatory Process*, Section 3.3.2, item 6, p.6.

- b? Identifying any SSCs for which achievement of design requirements (including CORAMI) will be technically challenging. (Note that this part of the review supports the evaluation of the adequacy of the projected safety basis.)

Review Considerations

Review Consideration 1 - SSC Design

The Reviewers will verify on a sampling basis that the preliminary design of the SSCs is consistent with the roles assigned to them in the hazards assessment and accident analysis. For example, if a given SSC is required to prevent lethal radiation exposure to workers, consideration should be given in the design to such practices as defense-in-depth, inherent or passive safety, or other appropriate design principles from the Top-Level Safety Standards and Principles. The Reviewers will also verify that important-to-safety SSCs have been identified for hazards and control measures that require SSCs. The Reviewers will assess if the Contractor has considered the “two over one” rule⁷⁵ in the design of SSCs. That is, the function of a high priority safety SSC should not be compromised by proximity to or dependence upon a lower priority SSC.

Review Consideration 2 - Open Issue Identification

The Reviewers will identify any SSCs for which achievement of design requirements (including CORAMI) will be technically challenging. If a developmental or unproven method is required to control a given safety hazard, the specific SSC will be recorded by the Reviewers for possible inclusion in open issues identified in the ISE. Such open issues are not necessarily unresolvable, but may require continued review by the RU as the Contractor progresses toward Authorization for Construction and Operation.

6.7 CORAMI

Evaluation Criterion⁷⁶

“The confidence associated with safety-related aspects of constructability, operability, reliability, availability, maintainability, and inspectability”

Review Intent

The intent of this section of the review is to determine the ability of the Contractor to complete the project with adequate safety by evaluating the design for constructability, operability, reliability, availability, maintainability and inspectability of safety functions (controls and SSCs).

Review Considerations

Review Consideration 1 - Constructability

The Reviewers will determine whether the Contractor has identified any impediments to constructing controls and SSCs important-to-safety.

Review Consideration 2 - Operability

The Contractor’s SRD submittal package included a hazards analysis. If that hazards analysis currently includes a HAZOPs (Hazards and Operability) analysis, the Reviewers will determine whether operability issues related to safety have been raised and/or resolved. The Reviewers may examine the Contractor’s assessment of operability. Issues may include:

⁷⁵ NRC Regulatory Guide 1.29, Seismic Design Classification, Revision 3, September, 1978.

⁷⁶ *Regulatory Process*, Section 3.3.2, item 9, p.6.

- unusual reliance on administrative controls, contact maintenance, or interface support; or
- vulnerability to single failures (such as melter failure), frequent maintenance and repair, limited margins or reserve capacity, limited surge accommodation, adequate product storage, waste stream accommodation, etc.

Review Consideration 3 - RAMI

The Reviewers will evaluate the design against the following *Top-Level Safety Standards and Principles*:

Reliability⁷⁷

“Reliability targets should be assigned to structures, systems, and components or functions important-to-safety. The targets should be consistent with the roles of the structures, systems, and components or functions in different accident conditions. Provision should be made for appropriate testing and inspection of structures, systems, and components for which reliability targets have been set.”

Availability, Maintainability, and Inspectability⁷⁸

“Structures, systems and components important-to-safety should be designated, designed and constructed for appropriate inspection, testing, and maintenance throughout their operating lives to verify their continued acceptability for service with an adequate safety margin.”

6.8 Initial Safety Analysis Report

This portion of the review integrates the findings of many of the other sections of this guide and performs a top-level assessment of the adequacy of the projected safety basis for the facility and its operation along with an assessment of the resolvability of open issues. The metric for “adequate safety” in this review should be observable evidence of conformance to the *Top-Level Safety Standards and Principles*.

Evaluation Criteria⁷⁹

“Adequacy of the projected safety basis for the facility and its operation;

The resolvability of open issues, ...”

Review Intent of the Criteria

The intent of this section of the review is to assess the adequacy of the safety basis and the resolvability of the open issues associated with the project by:

- Evaluating the adequacy of the safety basis for the facility. Consideration should be given to the adequacy of the approach for controlling hazards. The evaluation will address performance with respect to the integrated safety/operational environment;
- Identifying any open issues/significant technical risks associated with achieving an adequate safety basis (e.g., in the control of hazards [Section 6.3], in accommodation of technically challenging control measures identified in the analysis of design-basis events [Section 6.5], and

⁷⁷ *Regulatory Process*, Section 4.2.7.1, p.11.

⁷⁸ *Ibid.*, Section 4.2.7.2, p.11.

⁷⁹ *Ibid.*, Section 3.3.2, items 7 and 10, p.6.

in the identification and design of SSCs [Section 6.6]. Make an assessment of the resolvability of open issues and a qualitative assessment of the technical risks;

- c? Evaluating the projected effectiveness of protection of the public, workers, and the environment; and
- d? Verifying that there is consistency with the requirements of Sections 6.1-6.7 above.

Review Considerations

The results of this set of Review Considerations will be summarized briefly, identifying the strengths and weaknesses in the Contractor's approach for controlling hazards. Specific failures to conform to the Top-Level Safety Standards and Principles will be documented.

Review Consideration 1 - Physical Design

The Reviewers will identify on a sampling basis any features of the physical design which have unusual dependence on, or unique vulnerabilities to: active systems; SSCs important-to-safety; interface support; monitoring; maintenance timing; administrative controls; emergency preparedness; secondary control requirements; etc.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the physical design. To accomplish this task, the Reviewers will consider the results of the review performed in Section 6.1.1 (Design Description) in light of the review results for section 6.1.3 (Site Description). This Review Consideration is at a high level (overall plant layout on the site), since more Detailed Reviews of structures, systems and components or equipment important-to-safety are performed in the following three Review Considerations.

Review Consideration 2 - Structures Important-to-Safety

The Reviewers will determine if the structures the Contractor identified as important-to-safety are adequate in limiting challenges arising from structural failures and minimize compensatory measures such as emergency evacuation plans, excessive confinement, etc.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the structures important-to-safety. To accomplish this task, the Reviewers will consider the results of the review performed in Section 6.1.1.1 (Facility Description) which pertain to structures important-to-safety. The Reviewers may consider this information in light of the results of reviews described in Sections 6.3 (Hazards Assessment and Control), 6.4 (Selection of Design-Basis Events), 6.5 (Analysis of Design-Basis Events) and 6.6 (Adequacy of SSC Categories).

Review Consideration 3 - Systems Important-to-Safety

The Reviewers will determine if the Contractor has placed limited reliance on systems important-to-safety, has utilized appropriate standards for Reliability, Availability, Maintainability, and Inspectability (RAMI), has adopted low technology risk systems, and accommodates good human factors practices.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the systems important-to-safety. To accomplish this task, the Reviewers may consider the results of the review performed in Section 6.1.1.2 (Systems Description) which pertain to systems important-to-safety. The Reviewers might consider this information in light of the results of reviews described in Sections 6.3 (Hazards Assessment and Control), 6.4 (Selection of Design-Basis Events), 6.5 (Analysis of Design-Basis Events), and 6.6 (Adequacy of SSC Categories).

Review Consideration 4 - Components or Equipment Important-to-Safety

The Reviewers will determine whether the Contractor has placed limited reliance on components or equipment important-to-safety, has utilized appropriate standards for RAMI, has adopted low technology risk equipment, and accommodates good human factors practices.

The Reviewers may determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the components or equipment important-to-safety. To accomplish this task, the Reviewers might consider the results of the review performed in Section 6.1.1.3 (Process Description) which pertain to components or equipment important-to-safety. The Reviewers might consider this information in light of the results of reviews described in Sections 6.3 (Hazards Assessment and Control), 6.4 (Selection of Design-Basis Events) and 6.6 (Adequacy of SSC Categories).

Review Consideration 5 - Operating Modes and Conditions

The Reviewers will determine if the Contractor has demonstrated a reasonably complete consideration of hazards, events, and exposures arising from all expected modes of operation and associated conditions.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to operating modes and conditions. To accomplish this task, the Reviewers may consider the results of the review performed in Section 6.1.2 (Operations Description) which pertain to operating modes and conditions. The Reviewers may consider this information in light of the results of reviews described in Sections 6.3 (Hazards Assessment and Control), 6.4 (Selection of Design-Basis Events) and 6.6 (Adequacy of SSC Categories).

Review Consideration 6 - Off-Normal Operational Events

The Reviewers will determine if the Contractor has provided a reasonably complete consideration of events, minimized the challenges to the SSCs (magnitude and frequency), and identified adequate margins of safety.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to off-normal operational events. To accomplish this task, the Reviewers may consider the results of the review performed in Section 6.3 (Hazards Assessment and Control) which pertain to off-normal operational events.

Review Consideration 7 - External Events

The Reviewers will determine if the Contractor provided a reasonably complete consideration of external events, minimized vulnerabilities, provided adequate margins to standards and other specified limits, and has shown limited consequences to such events.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to external events. To accomplish this task, the Reviewers may consider the results of the review performed in Section 6.4 and 6.5 (Selection of Design-Basis Events and Analysis of Design-Basis Events) which pertain to external events. The Reviewers may consider this information in light of the results of reviews described in Sections 6.3 (Hazards Assessment and Control), and 6.6 (Adequacy of SSC Categories).

Review Consideration 8 - Safety Analysis and Results

The Reviewers will determine if the Contractor has utilized acceptable analysis methods, has shown adequate margins to standards and other specified limits, has demonstrated that safety goals are achievable, and has an adequate treatment of the site boundary and populations.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the results of the safety analysis. To accomplish this task, the Reviewers may consider the results of the review performed in Sections 6.3 (Hazards Assessment and Control).

Review Consideration 9 - Major Uncertainties in Data and Analysis

The Reviewers will identify sources of uncertainties which limit the ability to project (1) the consequences of design-basis events or, (2) the technical requirements of SSCs and controls.

The Reviewers will determine whether the projected safety basis for the facility (safety envelope) is adequate with regard to the major uncertainties in data and analysis. To accomplish this task, the Reviewers may determine if the contractor has identified and quantified those uncertainties. The Reviewers will summarize briefly the uncertainties, including additional uncertainties identified. If uncertainties lead to specific uncertainties in the Contractor's ability to conform to the *Top-Level Standards and Principles*, these uncertainties will be documented.

6.9 Draft Deactivation Plan

A draft deactivation plan is required to be part of the ISA submittal package.⁸⁰ The Department's objective in requesting a draft deactivation plan at the end of Part A is to ensure that the Contractor's firm fixed-price bid for Part B has a sound safety basis in estimating the deactivation portion of the overall cost. Sufficient detail is required in the draft plan to achieve this objective. The Regulatory Unit will not review the cost estimate at this time; however, since that regulatory action is anticipated only during application for authorization for deactivation.

Evaluation Criterion⁸¹

"The adequacy of the draft deactivation plan..."

Review Intent

- a? Evaluate the extent that deactivation safety (e.g., minimizing radiological exposure and generation of radioactive or mixed waste during decontamination) has been addressed in design and will be addressed early and considered prior to construction;
- b? Evaluate the Contractor's commitment to comply with approved standards for deactivation and verify that there is consistency with the selected standard such as sections of the Contract, and
- c? Evaluate the safety-related aspects of the Contractor's Draft Deactivation Plan against those requirements specified in Standard 8 of the Contract which have safety implications.

Review Considerations

Review Consideration 1- Requirements⁸²

The Reviewers will determine whether the Contractor has identified the applicable design codes, standards, regulations, and DOE Orders which are expected to be part of the SRD related to deactivation. The intent is to identify only the requirements that are specific for deactivation and tailored to the hazards and planned work, and not comprehensively list all industrial standards, codes or criteria.

⁸⁰ *Regulatory Process*, Section 4.2.2, item 11, p.14.

⁸¹ *Ibid.*, Section 3.3.2, item 11, p.6.

⁸² DOE-STD-3009-94, Chapter 16.2, p.122.

Review Consideration 2- Description of Planned Deactivation Activities⁸³

The Reviewers will examine the Contractor's documentation for planning of design or modifications or operations that minimize the potential for spread of contamination or that would complicate or reduce effectiveness of future deactivation or environmental restoration activities. The Contractor's assessment of future deactivation activities must be based on an evaluation of the type and magnitude of hazards and the complexity of processes. The Contractor's evaluation should consider the vulnerabilities to normal and abnormal events and operational plans to minimize contamination and prevent an increase in residual risk during or after decommissioning. The evaluation, however, is conceptual in nature and does not require the extent of documentation required of a SAR hazard analysis.⁸⁴

The Reviewers will determine if the Contractor has planned to minimize the spread of radioactive contamination during operations by incorporating any design-for-decommissioning features into the facility design.⁸⁵

Review Consideration 3 - ALARA⁸⁶

The Reviewers will determine if the applicant has planned to adopt a health physics program for keeping individual and collective occupational radiation exposure ALARA during deactivation.

Review Consideration 4 - Health Physics Program⁸⁷

The Reviewers will confirm that the Contractor's health physics program that is to be in effect during deactivation is described. The program should include QA provisions such as audits, inspections, or management reviews. The criteria for selecting equipment and instrumentation for performing radiation and contamination surveys and personnel monitoring, including special instruments for detecting low levels of radiation, should be provided.

Review Consideration 5 - Radioactive Waste Management⁸⁸

The Reviewers will confirm processes and systems to be used for handling, storing, and disposing of radioactive waste are described.

Review Consideration 6 - Contract Standard

The Reviewers will consider Standard 8⁸⁹ of the Contract when addressing Review Considerations 1 - 5, above.

6.10 Outlines for Part B

The *Regulatory Process* calls for an evaluation of:

“The adequacy of the outlines of various plans, programs, and requests that will be generated and implemented in Part B.”⁹⁰

⁸³ Draft NUREG 1520, Section 11.1.4.3.3, p.11.1-10 through 12.

⁸⁴ DOE-STD-3009-94, Chapter 16.3, p.122.

⁸⁵ Draft NUREG 1520, Section 11.1.4.3.2, p.11.1-9.

⁸⁶ Ibid., Section 11.1.4.3.4, item 2, p.11.1-13.

⁸⁷ Draft NUREG 1520, Section 11.1.4.3.4, item 3, p.11.1-13.

⁸⁸ Ibid., Section 11.1.4.3.4, item 5, p.11.1-14.

⁸⁹ See Section 9.1, of this Guide.

⁹⁰ *Regulatory Process*, Section 3.3.2, item 8, p.6.

This includes outlines for:

- a? Construction Authorization Request; *[LMAES only]*
- b? Operating Authorization Request; *[LMAES only]*
- c? Emergency Response Plan;
- d? Unreviewed Safety Question Plan;
- e? Conduct of Operations Plan;
- f? Technical Safety Requirements;
- g? Training and Qualification Plan;
- h? Maintenance Implementation Plan;
- i? Occurrence Reporting Procedures;
- j? Environmental Radiological Protection Program;
- k? Radiation Protection Program;
- l? Operational Analysis and Assessment Reports;
- m? Deactivation Safety Assessment; and *[LMAES only]*
- n? Deactivation Authorization Request *[LMAES only]*

Note: (1) Summaries of each required outline are provided in Section 8.

(2) Detailed examples of acceptable outlines for each area are provided in Section 9.

Review Intent

The intent of this section of the review is to assess the adequacy of the Contractor's outlines. The Reviewers will evaluate the outlines against the Contract, against standards in the SRD, and against management plans in the ISMP to ensure consistency of the projected programs and plans with technical requirements for scope and extent of measures to be taken.

Detailed examples of acceptable outlines for each area are provided in Section 9 and may be used as tools in conducting this portion of the review. However, many alternatives exist in the format and content of each outline, and the Reviewers may draw on their own independent expertise to evaluate the Contractor's proposed outline.

While the SRD is required to contain standards for the regulatory submittals (cf., DOE/RL-96-0003, *Regulatory Process*, Section 4.1.2), the ISA is required to contain outlines of these major regulatory submittals because it was anticipated that the standards might not describe their format and content as fully as the requested outlines.

These outlines are called for in the Contract because specific DOE Orders, DOE Standards, or NRC Review Plans and Regulatory Guides covering these items are not incorporated into the Contract for the TWRS Privatization Program. Therefore the Reviewers will determine if the Contractor's Outlines for these plans, programs, reports, procedures, assessments and authorization requests are adequate.

The Contractor is expected to provide enough topics and sufficient detail in each outline for the Reviewers to determine if the scope, breadth and depth of the product will be sufficient to achieve authorization for construction, operation and deactivation.

7. INITIAL SAFETY EVALUATION RESULTS

The Initial Safety Evaluation Report (ISER) is provided to both DOE, the customer, and to the Contractor. The ISER will be used by DOE, the customer, as described in the *Regulatory Process*:

“The results of this evaluation will be available to DOE, the customer, as input in choosing the Contractors to authorize to perform the Part B work. This evaluation will

also provide a perspective on the regulatory risks associated with the Contractor's firm-fixed-price proposal.”⁹¹

The Glossary of the *Regulatory Process* defines the ISER as:

Initial Safety Evaluation Report. The document, approved and issued by the Director of the Regulatory Unit, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

The Initial Safety Evaluation provides DOE, the customer, with a clear and concise summary of the regulatory risks associated with the Contractor's waste processing approach. In this regard, a summary chapter should be provided in the ISER that defines major themes that are identified as a result of the ISA review. While there may be many detailed issues that result from the review, the Reviewers consolidate their results in this section and determine if such themes can be identified.

The ISER will also be provided to the Contractor. The Contractor may use this report to gain insights into areas where the Regulatory Unit believes work needs to be done to successfully accomplish authorization for either construction, operation, or deactivation. As such, the ISER should summarize major findings and provide the more detailed findings of the review.

Rejection of the ISA following the Acceptability Review involves the following activities:

“If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached. Rescheduling the review may not permit a full review of the ISA because of the constraints of the overall procurement schedule. If so, the partial review and associated results will be summarized in the ISER along with all open issues.”⁹²

Whether the ISA is rejected or not the *Regulatory Process* states:

“Insufficient information either in scope or depth to facilitate the initial safety evaluation may result in open issues that will be noted in the ISER.”⁹³

8. OUTLINE SUMMARIES

The Contractor is expected to provide enough topics and sufficient detail in each outline for the Reviewers to determine if the scope, breadth and depth of the product will be sufficient to achieve authorization for construction, operation and deactivation.

The below listed outline summaries provide the reviewers with the minimum content that the Contractors are to include in their outlines (8.1, 8.2, 8.13 and 8.14 apply to LMAES only). Two authoritative sources can be used in assembling the outlines required in the ISA. In some instances (e.g., Authorization for Construction), the Contract provides detailed insight into what may be included in the outline. In other instances, the Contractor's SRD defines standards that may be used as the basis for outlines in the ISA. In cases where both sets of information are available, the Contractor's more detailed standard may augment the Contractual requirements. In cases where neither Contractual language nor approved standards from the SRD address the outline in question, Section 9 provides example outlines developed from other source information that may be used by the Reviewers to evaluate the submittal. This source material is not mandatory, but provides an acceptable outline methodology. The Contractor may use other methodologies, provided the scope and depth is appropriately tailored to the hazards of the facility.

⁹¹ *Regulatory Process*, Section 3.3.2, p.5.

⁹² *Ibid.*, Section 4.2.1, p. 13.

⁹³ *Ibid.*, Section 3.3.2, p. 6.

8.1 Construction Authorization Request

At a minimum, the Outline for the Construction Authorization Request should address the Submittal Requirements identified in the *Regulatory Process*.⁹⁴ This includes descriptions of the Contractor's site, natural-phenomena and man-made external hazards; high-level radioactive waste handling and treatment processes; facility SSCs, planned safety-related testing, etc., including a Preliminary Safety Analysis Report. A complete list of requirements is repeated in Section 9.2 for the Reviewers' convenience.

8.2 Operating Authorization Request

At a minimum, the Outline for the Operating Authorization Request should address the Submittal Requirements identified in the *Regulatory Process*.⁹⁵ This includes final descriptions of the Contractor's site, natural-phenomena and man-made external hazards, high-level radioactive waste handling and treatment processes, facility SSTs, etc., including a Final Safety Analysis Report (FSAR). A complete list of submittal requirements is repeated in Section 9.3 for the Reviewers' convenience.

8.3 Emergency Response Plan

The *Top-Level Safety Standards and Principles* states:

“While the scope of the regulation is predominantly limited to the Contractor's activities from initial design through deactivation, it also must include the Contractor's [sic] coordination with the DOE/RL's integrated emergency response.”⁹⁶

The Reviewers will therefore determine whether the Contractor's emergency response plan is compatible with RL's integrated emergency response. RL's emergency response is based on DOE Order 5500.3A.⁹⁷ This DOE Order is not mandated for TWRS Privatization Contractors. The elements of the Order are duplicated in Section 9.4 for Reviewers' convenience.

8.4 Unreviewed Safety Question Plan

The Reviewers will refer to the treatment of Unresolved Safety Questions⁹⁸ in the approved ISMP, if any.⁹⁹ In the event that additional insight is needed to review the ISA Outline for the Unreviewed Safety Question Plan, the Reviewers may consider elements related to unreviewed safety questions in the Draft rules,¹⁰⁰ and in DOE Order 5480.21.¹⁰¹ This DOE Order is not mandated for TWRS Privatization Contractors. An outline of the elements of the Order is provided in Section 9.5 for the Reviewers' convenience.

⁹⁴ *Regulatory Process*, Section 4.3.2, items 1-20, pp. 15-16.

⁹⁵ *Ibid.*, Section 4.4.2, p.18.

⁹⁶ *Top-Level Safety Standards and Principles*, Section 1.2, p.1.

⁹⁷ DOE Order 5500.3A, Planning and Preparedness for Operational Emergencies, 4/30/91.

⁹⁸ An unresolved safety question exists when a positive determination is made that an unreviewed safety question may have an adverse impact on the safety of the facility.

⁹⁹ *ISMP Review Guidance*, Section 6.2, Attribute 16, p. 11.

¹⁰⁰ Draft 10 CFR Part 830, 8/25/95 working draft, 830.112 - Unreviewed Safety Questions

¹⁰¹ DOE Order 5480.21, Unreviewed Safety Questions, 12/24/91, Section 10 - Program Requirements, p.10.

8.5 Conduct of Operations Plan

The Reviewers will consider the management standard identified in the SRD, if any, when reviewing the Conduct of Operations Plan Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules¹⁰² and the table of contents in DOE Order 5480.19¹⁰³ as acceptable standards for the Conduct of Operations Outline. The elements of the Order are reproduced in Section 9.6 for the convenience of the Reviewers.

8.6 Technical Safety Requirements

The Reviewers will consider the management standard identified in the SRD, if any, when reviewing the Technical Safety Requirements Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules¹⁰⁴ and DOE Order 5480.22, Technical Safety Requirements, as examples of the elements that may be included in the Contractor's Technical Safety Requirements Outline. The Reviewers may use that Order as a tool to evaluate the Contractor's draft outline but should not necessarily expect strict adherence. The elements of DOE Order 5480.22 Order are repeated in Section 9.7 for the Reviewers' convenience.

8.7 Training and Qualification Plan

The Reviewers will consider the management standard identified in the SRD, if any, when reviewing the Training and Qualification Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules,¹⁰⁵ the USNRC Regulatory Guide,¹⁰⁶ and DOE Order 5480.20.¹⁰⁷

First, the Reviewers may consider USNRC Regulatory Guide 3.52 as one possible acceptable standard for the Training and Qualification Plan Outline. This outline includes:

- 1? Organization and Management of the Training System
- 2? Trainee Selection
- 3? Conduct of Needs/Job Analysis and Identification of Tasks for Training
- 4? Development of Learning Objectives as the Basis for Training
- 5? Organization of Instruction Using Lesson Plans and Other Training Guides
- 6? Evaluation of Trainee Mastery of Learning Objectives
- 7? Conduct of On-the-Job Training
- 8? Systematic Evaluation of Training Effectiveness

Second, the Reviewers may also consider the training and qualification requirements in DOE Order 5480.20.¹⁰⁸ This outline includes:

¹⁰² Draft 10 CFR Part 830, 8/25/95 working draft, 830.310 - Conduct of Operations

¹⁰³ DOE Order 5480.19, Conduct of Operations Requirements for DOE Facilities, 7/9/90

¹⁰⁴ Draft 10 CFR Part 830, 8/25/95 working draft, 830.320 - Technical Safety Requirements

¹⁰⁵ Draft 10 CFR Part 830, 8/25/95 working draft, 830.330 - Training and Qualification

¹⁰⁶ Office of Nuclear Material Safety and Safeguards. USNRC Regulatory Guide 3.52, *Standard Format and Content for the Health and Safety Sections of License Applications for Fuel Cycle Facilities*, Revision 2 [DRAFT], January 1995. Section 3.4 - Training and Qualification. (*Regulatory Guide*).

¹⁰⁷ DOE Order 5480.20, Personnel Selection, Qualification, and Training Requirements For DOE Nuclear Facilities, 11/15/94, (*DOE Order 5480.20*)

¹⁰⁸ Ibid., Chapter IV - Non-Reactor Nuclear Facility Personnel, p. IV-1 through IV-8.

- 1? Purpose
- 2? Entry-Level Requirements
- 3? Medical Examination Requirements
- 4? Specific Training Requirements
- 5? Operator, Fissionable Materials Handler, And Supervisor Proficiency Requirements.

Further information from USNRC Regulatory Guide 3.52 and DOE Order 5480.20 is provided in Sections 9.8 and 9.9 for the convenience of the Reviewers.

8.8 Maintenance Implementation Plan

The Reviewers will consider the appropriate management standard identified in the SRD, if any, when reviewing the Maintenance Implementation Plan Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules¹⁰⁹ and DOE Order 4330.4B¹¹⁰ as tools when evaluating the Contractor's proposed outline for a maintenance implementation plan. Top-level aspects of the Order are repeated in Section 9.10 for the convenience of the Reviewers.

8.9 Occurrence Reporting Procedures

The Reviewers will consider the management standard identified in the SRD when reviewing Occurrence Reporting Procedures Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules¹¹¹ and the definitions and scope of DOE Order 5000.3B¹¹² with regard to occurrence reporting. Material is repeated from DOE Order 5000.3B in Section 9.11 for the Reviewers' convenience.

8.10 Environmental Radiological Protection Program

The Reviewers may consider the organization suggested in the draft Rule 10 CFR 834¹¹³ in evaluating the Contractor's Outline for the environmental radiological program. According to the Rule, the content of the Environmental Radiological Protection Program (ERPP) shall address each requirement of 10 CFR 834, including:

- 1? Identity of existing or anticipated DOE activities subject to the requirement
- 2? Measures to be used in implementing the requirement
- 3? Methods to be used in monitoring, reporting, and recording compliance with the requirement
- 4? ALARA Program
- 5? Environmental monitoring
- 6? Ground water protection
- 7? Radiological protection in the management of radioactive waste and property containing residual radioactive material.

Further information can be found in Section 9.12.

¹⁰⁹ Draft 10 CFR Part 830, 8/25/95 working draft, 830.340 - Maintenance Management

¹¹⁰ DOE Order 4330.4B, Maintenance Management Program, 2/10/94, Section 10, Requirements, pp.7-9.

¹¹¹ Draft 10 CFR Part 830, 8/25/95 working draft, 830.350 - Occurrence Reporting and Processing of Operations Information

¹¹² DOE Order 5000.3B - Occurrence Reporting and Processing of Operations Information, 1/19/93.

¹¹³ 10 CFR 834 - Radiation Protection of the Public and the Environment, Subpart A -- General Provisions, §834.5; Environmental Radiological Protection Program. Federal Register Notice Docket No. EH-RM-93-834 RIN 1901-AA38, Issued in Washington, DC on August 28, 1995.

8.11 Radiation Protection Program

The Reviewers will consider the management standard identified in the SRD when reviewing the Radiation Protection Program Outline. If additional information is needed to conduct the review, the Reviewers may consider the draft DOE Rules,¹¹⁴ and the law.¹¹⁵ The Reviewers may also evaluate the Outline using DOE Notice 441.1¹¹⁶ as one example of an acceptable approach. Elements of the Notice are repeated in Section 9.13 for the Reviewers' convenience.

8.12 Operational Analysis and Assessment Reports

The Reviewers will consider standards identified in the SRD when reviewing the Operational Analysis and Assessments Reports Outline. The Reviewers may also consider the requirements identified in the *Regulatory Process* in evaluating this Outline. The requirements are repeated in Section 9.14 for the Reviewers' convenience.

8.13 Deactivation Safety Assessment

The Reviewers will examine the Deactivation Safety Assessment outline in the context of its description in the *Regulatory Process*:

“... the Deactivation Authorization Request, which includes a Deactivation Safety Assessment... submitted by the Contractor under oath and affirmation. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action...”¹¹⁷

The Contractor's deactivation safety assessment outline may be included in the Draft Deactivation Plan submitted as part of the ISA. If this is the case, the Reviewers may refer to Section 6.9 of this Guide.¹¹⁸

One possible standard against which the Outline could be judged is draft 10 CFR 830.110.¹¹⁹ This draft rule requires that the scope of safety analysis reports shall:

- Define the safety basis;
- Document the logic of its derivation;
- Justify its adequacy;
- Document the assumptions employed in the safety analysis; and
- Set forth the results of the safety analysis.

The hazard analysis should address:

- Hazard classification (Category 1, 2 or 3 for unmitigated releases)
- Inventory of hazardous material
- Evaluation of potential releases

The Reviewers may refer to the draft rule if clarification is needed to evaluate the proposed outline.

¹¹⁴ 10 CFR 834, 3/93 Draft, Radiation Protection of the Public and the Environment

¹¹⁵ 10 CFR 835, Occupational Radiation Protection

¹¹⁶ DOE Notice 441.1, Radiological Protection for DOE Activities, 9/29/95.

¹¹⁷ *Regulatory Process*, Section 3.3.6, item 4, p.10.

¹¹⁸ Review Consideration 2 - Description of Planned Deactivation Activities.

¹¹⁹ Draft 10 CFR Part 830 -- Nuclear Safety Management, Section 110 -- Safety Analysis Report

8.14 Deactivation Authorization Request Submittal Requirements

At a minimum, the Outline for the Deactivation Authorization Request should address the Submittal Requirements identified in the *Regulatory Process*.¹²⁰ The requirements are repeated in Section 9.15 for the Reviewers' convenience.

9. Contract Excerpts and Sample Outlines

This section contains detailed examples of acceptable outlines for each area and may be used as tools in conducting this portion of the review. However, many alternatives exist in the format and content of each outline, and the Reviewers may draw on their own independent expertise to evaluate the Contractor's proposed outline.

The following subsections provide either excerpts taken directly from the Contract (requirements) or sample outlines (not requirements). The preparers of this Guide chose to use italicized text to offset that text taken directly from the Contract. The sample outlines (Subsections 9.4 - 9.11 and 9.13 - 9.15) are examples provided for the reviewers' convenience and are not necessarily the only outline format the Contractor may elect to use. The occasional use of the word "requirement" in these later subsections is only an artifice of the language of the Order being duplicated. When used in this context, the language does not reflect a requirement of the TWRS Privatization Contract.

9.1 Contract Standard 8

The purpose of this Standard is to describe the requirements for the Deactivation Plan to be submitted in Part A and the facility deactivation to be performed in Part B.

a. During Part A, the Contractor shall submit a Deactivation Plan for review and approval. The Deactivation Plan shall describe how the Contractor-provided facilities and equipment shall be deactivated, and discuss the following topical areas listed below.

1) Facility End-Point Criteria: the physical state at the end of facility deactivation, including detailed end-points for the site, facilities, systems/equipment, and documentation. Minimum facility end-point criteria shall include the following:

(a) Remediation of all hazardous and dangerous chemicals and radioactive site contamination that results from Contractor activities.

(b) Removal of inventories of hazardous and dangerous chemicals, and radioactive materials.

(c) Removal and stabilization of residual radioactive source terms to reduce risk to at least a low hazard facility in accordance with DOE Order 5480.23 and DOE-STD-1027-92. Primary facility and process system requirements include:

- Leaving in-place major process equipment, piping, and deactivated electrical systems.*

¹²⁰ *Regulatory Process*, Section 4.6.2, items 1-8, p.23.

- *Flushing internal surfaces of all process systems to remove water-soluble or transportable chemical and radioactive material.*
 - *Decontaminating and cleaning external surfaces of all process equipment to minimize radioactive source terms.*
 - *Fixing any residual contamination on internal surfaces of the process facility to prevent mitigation.*
 - *Minimizing areas that require radiological or other controls.*
 - *Containing residual hazardous and dangerous chemicals and radioactive materials within existing confinement structures.*
- (d) *Removal of all Special Nuclear Material (SNM) to the practical extent possible. The quantity of nuclear materials remaining shall be no greater than Category IV-E levels established in DOE Order 5633.3B.*
- (e) *Leaving in-place all confinement structures with adequate capability to maintain deactivated status; stabilizing other structures to minimize weather and prevent animal intrusion; and providing safe, controlled access to all structures.*
- (f) *Providing the minimum number of active systems required to maintain deactivated status to accomplish the following:*
- *Deactivation, consolidation, or isolation of all facility and process systems to the maximum extent possible while maintaining contamination control.*
 - *Removal of all combustible and flammable materials; reduction or elimination of all fire protection, monitoring, and alarm systems to the maximum extent possible.*
 - *Elimination or minimization of all utility systems not required to maintain deactivated status.*
- (g) *Removal of separable equipment, materials, and tools for other use or salvage.*
- (h) *Installation of monitoring systems for interim surveillance for use prior to Decontamination and Decommissioning (D&D)/RCRA Closure.*
- (i) *Provision of deactivated facility configuration and operations documentation that defines: process and facility configuration; level and location of residual contamination; system capabilities that remain for D&D/RCRA Closure; and operational requirements prior to D&D/RCRA Closure.*
- 2) *Final Facility and Site Characterization Survey:* *the methodology to establish location of residual contamination and contamination level.*

- 3) Operational and Maintenance Requirements of the Deactivated Facility: the required information to maintain the deactivated facility, including operations and maintenance requirements for active systems, maintenance requirements to assure structural integrity, and procedures necessary to reactivate essential systems for eventual D&D/RCRA Closure.
- 4) Facility Turnover: the methods to verify achievement of end-point criteria, protocols for formal turnover of the facility and site to DOE, and the transfer of facility operating records and other documentation.

b?? Upon completion of waste treatment services in Part B, the Contractor shall deactivate Contractor-provided facilities in conformance with the approved Deactivation Plan, Interface Description 10, Deactivated Facility and Site, and the deactivation authorization provided by the DOE Regulatory Unit.

9.2 Construction Authorization Request Requirements

...the Construction Authorization Request submittal package...shall consist of the following documentation:

- 1) Description of the Contractor's site and its location within the Hanford Site;
- 2) Description of natural-phenomena and man-made external hazards at the Contractor's site, the selected design-basis external events, and the rationale for their selection;
- 3) Description of high-level radioactive waste handling and treatment processes;
- 4) Description of planned facility operations;
- 5) Description of facility structures, systems, and components including those designated as important-to-safety;
- 6) The current SRD and the ISMP and an assessment of compliance to the SRD and the ISMP (note the changes relative to the SRD and ISMP approved by the regulation action of Section 4.1);
- 7) Detailed design data and design drawings;
- 8) Analysis of radiological, nuclear, and process hazards for the final design;
- 9) Description of facility features and functions provided to control the radiological, nuclear, and process hazards;
- 10) Description of the range of off-normal events and postulated accidents that could initiate internal to the Contractor's facility, the selected design-basis internal events, and the rationale for their selection;
- 11) Analysis of hazards-control features during all expected facility operating modes, off-normal conditions, and design basis internal and external events;
- 12) Potential safety limits and the justification for their selection;
- 13) Description of planned safety-related testing to be performed, including the purpose of each test, expected data, and a description of the test and associated equipment;
- 14) Description of quality assurance program, including implementation procedures, employed during the design, and to be employed during construction, safety-related testing, and pre-operational testing;
- 15) A PSAR that
 - a? Defines the analyzed safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions

- made, uncertainties in data and analyses, safety limits, and operating limits;
- b? Demonstrates that the facility should perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations should be met; and
- c? Demonstrates that adequate protection of the public, the workers, and the environment should be achieved;
- 16) The Contractor's technical and experience qualifications to construct the plant;
- 17) The Contractor's financial capability to construct the plant;
- 18) Description of the D&D features provided in the design and the final deactivation plan;
- 19) The procedures to be used to implement the construction and pre-operational testing portions of the SRD and the ISMP;
- 20) Drafts of the
 - a? Emergency Response Plan;
 - b? Unreviewed Safety Question Plan;
 - c? Conduct of Operations Plan;
 - d? Technical Safety Requirements;
 - e? Training and Qualification Plan;
 - f? Maintenance Implementation Plan;
 - g? Occurrence Reporting Procedures;
 - h? Environmental Radiological Protection Program; and
 - i? Radiation Protection Program

9.3 Operating Authorization Request Submittal Requirements

... the Operating Authorization Request submittal package... shall consist of the following documentation:

- 1) Final description of the Contractor's site and its location within the Hanford Site (emphasize changes from the construction authorization basis);
- 2) Final description of the natural-phenomena and man-made external hazards at the Contractor's site, selected design-basis external events, and rationale for their selection (emphasize changes from the construction authorization basis);
- 3) Final description of the high-level radioactive waste handling and treatment processes (emphasize changes from the construction authorization basis);
- 4) Final description of the facility operations (emphasize changes from the construction authorization basis);
- 5) Final description of the facility structures, systems, and components including those designated as important-to-safety (emphasize changes from the construction authorization basis);
- 6) The final SRD and ISMP, and an assessment of compliance to the SRD and the ISMP (emphasize changes from the construction authorization basis);
- 7) Final design data and design drawings that clearly indicate the safety features of the plant and their characteristics (emphasize changes from the construction authorization basis);
- 8) Final analysis of radiological, nuclear, and process hazards as controlled by the engineered safety features (emphasize changes from the construction authorization basis);
- 9) An FSAR that
 - a) Fully defines the analyzed safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions,

- operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions made, uncertainties in data and analyses, safety limits, and operating limits;*
- b) Demonstrates that the facility will perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations will be met; and*
 - c) Demonstrates that adequate protection of the public, the workers, and the environment will be achieved;*
- 10) The Contractor's technical and experience qualifications to operate the facility;*
 - 11) The Contractor's financial capability to operate the facility;*
 - 12) Final description of the D&D features provided in the design and any changes in the deactivation plan, including financial arrangements that have been made to ensure its implementation (emphasize changes from the construction authorization basis);*
 - 13) Procedures to be used to implement the operations portions of the SRD and ISMP;*
 - 14) Final Technical Safety Requirements and the rationale for their selection;*
 - 15) Final Training and Qualification Plan;*
 - 16) Certification that operations personnel are ready and able to perform their intended functions;*
 - 17) Description of the safety-related testing program, including pre-operational facility and equipment tests, and the results of the tests versus the test requirements and acceptance criteria;*
 - 18) Final description of the quality assurance program, including implementation procedures employed during the design, construction, safety-related testing, and pre-operational testing and documentation of the effectiveness of the QA program implementation in assuring that the facility is construction as intended;*
 - 19) Final description of the expected radiological effluents from the facility and the associated monitoring and reporting programs;*
 - 20) Final description of the expected radioactive wastes (non-product wastes) from facility operations and the associated storage, handling, and disposal programs;*
 - 21) Final Conduct of Operations Plan to be implemented during the facility operations phase and evidence that the plan is fully implemented;*
 - 22) Final operating procedures, including those for recovery from off-normal events;*
 - a? Unreviewed Safety Question Plan;*
 - b? Maintenance Implementation Plan;*
 - 23) Final submissions of the*
 - a) Unreviewed Safety Question Plan;*
 - b) Maintenance Implementation Plan;*
 - c) Occurrence Reporting Procedures;*
 - d) Environmental Radiological Protection Program;*
 - e) Radiation Protection Program;*
 - f) Emergency Response Plan and procedures;*
 - 24) Evidence that the intended emergency response capability is qualified and functional;*
 - 25) Final description of the physical protection program and associated physical and administrative features;*
 - 26??The Contractor's understanding of and commitment to comply with the provisions of the regulatory oversight program during the operations phase*

9.4 Elements of Order DOE Order 5500.3A - Planning and Preparedness for Operational Emergencies

- a. General. As part of the Emergency Management System, DOE elements and DOE contractors shall establish and maintain emergency management programs consisting of plans and

procedures for response to Operational Emergencies involving or affecting DOE facilities, including DOE transportation activities. These emergency management programs must be commensurate with the assessment of potential hazards and targets and must include the following elements: Emergency Response Organization, Offsite Response Interfaces, Operational Emergency Event Classes, Notification, Consequence Assessment, Protective Actions, Medical Support, Recovery and Reentry, Public Information, Emergency Facilities and Equipment, Training, Drills and Exercises, and Program Administration.

- b. Hazards Assessment. A hazards assessment shall be prepared and maintained for each facility and shall be used for emergency planning purposes. This hazards assessment provides the technical basis for the emergency management program and shall include information sufficient to determine the scope and extent of the program elements comprising the emergency management program for the respective facility.
- c. Program Elements. All DOE emergency management programs must include, as a minimum, the following program elements:
 - (1) Emergency Response Organization. An element with clearly specified authorities and responsibilities for emergency response and mitigation which must be established and maintained for each facility. It must have overall responsibility for the initial and ongoing response to, and mitigation of, an emergency.
 - (2) Off-site Response Interfaces. Provisions must be in place for interface and coordination with Federal, state, tribal, and local agencies and organizations responsible for off-site emergency response and for protection of the environment and the health and safety of the public.
 - (3) Operational Emergency Event Classes. Operational Emergencies involving or effecting DOE facilities must be characterized as one of the Operational Emergency classes (e.g., Alert, Site Area Emergency, or General Emergency) in accordance with DOE 5500.2B.
 - (4) Notification. Notification and communication of emergency information must be consistent with DOE 5000.3A and 5500.2B. Provisions must be in place for prompt initial notification of emergency response personnel and response organizations.
 - (5) Consequence Assessment. Provisions must be in place to adequately assess the actual or potential onsite and offsite consequences of an emergency.
 - (6) Protective Actions. Provisions must be in place for specific, predetermined actions to be taken in response to emergency conditions to protect onsite personnel and the public.
 - (7) Medical Support. Provisions must be in place for medical support for workers, including those with radiological and/or hazardous material contamination.
 - (8) Recovery and Reentry. Provisions must be made for recovery from an Operational Emergency and reentry into the affected facility.
 - (9) Public Information. An emergency public information program, consistent with DOE 5500.4, must be established and integrated into the emergency management program.
 - (10) Emergency Facilities and Equipment. Facilities and equipment, adequate support emergency response, must be established and maintained.
 - (11) Training. General training must be provided to all workers regarding Operational Emergencies, and specialized training must be conducted for all workers and be available to all regional Federal, state, tribal, and local emergency response organizations.

- (12) Drills and Exercises. A coordinated program of drills and exercises must be an integral part of the emergency management program.
- (13) Program Administration. Provisions must be in place for the continued administration of the emergency management program.
- d. Documentation. Program Senior Officials, Heads of Field Elements, and all managers/administrators of a DOE- or contractor-operated facility shall develop and maintain an emergency plan and associated procedures to document their emergency management program.

9.5 Elements of DOE Order 5480.21 - Unreviewed Safety Questions

- a. A contractor authorized to operate DOE nuclear facilities shall:
 - (1) Perform all safety evaluations required by paragraph (b) of this section to determine whether a situation involves a USQ;
 - (2) Prior to implementation of a proposed action, obtain PSO¹²¹ approval for situations determined to involve a USQ or a Technical Safety Requirements (TSR) change; and
 - (3) Develop and implement procedures to govern the need for, and the performance of, safety evaluations under this section.
- b. A safety evaluation shall be performed for:
 - (1) Temporary or permanent changes in the facility as described in the existing safety analyses;
 - (2) Temporary or permanent changes in the procedures as described in existing safety analyses; or
 - (3) Test or experiments not described in existing safety analyses.
- c. A situation involves a USQ if:
 - (1) The probability of occurrence or the consequences of an accident or malfunction of equipment important-to-safety previously evaluated in the facility safety analyses could be increased;
 - (2) The possibility for an accident or malfunction of a different type than any evaluated previously in the facility safety analyses could be created; or
 - (3) Any margin of safety, as defined in the bases of the TSRs, could be reduced.
- d. When a contractor identifies information that indicates a potential inadequacy of previous safety analyses or a possible reduction in the margin of safety as defined in the TSRs, the contractor shall:
 - (1) Notify the PSO of the situation upon discovery of the information;
 - (2) Make an evaluation in accordance with paragraphs a and c;
 - (3) Take action to place the facility in a safe condition until the safety evaluation is completed; and
 - (4) Submit the completed safety evaluation prior to removing any operational restrictions initiated pursuant to paragraph d(2)
- e. For all safety evaluations required under this section, a contractor shall:

¹²¹ Program Secretarial Officer (PSO). A senior outlay program manager, including the Assistant Secretaries for Conservation and Renewable Energy (CE), Defense Programs (DP), Fossil Energy (FE), Nuclear Energy (NE), and Environmental Restoration and Waste Management and the Directors of Energy Research (ER), Civilian Radioactive Waste Management (RW), and New Production Reactors (NP).

- (1) Document the basis for the USQ determination, utilizing the procedures provided for in paragraph a(3) of this section and the criteria of paragraph c;
- (2) Maintain documentation required by paragraph e(1) for the authorized operating period of the nuclear facility and ensure the complete transfer of all documentation to any subsequent contractor prior to termination of its contract;
- (3) Incorporate in the existing SAR, any changes that are needed as a result of the safety evaluation or any action taken; and
- (4) Submit to the PSO, on a schedule corresponding to the periodic updates of the SAR, a report of all situations for which a safety evaluation was required by this section and indicating all “changes” considered in a safety evaluation and implemented 6 months or more before the submittal date of the report.

9.6 Elements of DOE Order 5480.19 - Conduct of Operations Requirements for DOE Facilities

The table of contents in DOE Order 5480.19 is an acceptable standards for the Conduct of Operations Outline.

Chapter I. Operations Organization And Administration

1. Operations
2. Resources
3. Monitoring Policies Of Operating Performance
4. Accountability
5. Management Training
6. Planning For Safety

Chapter II. Shift Routines And Operating Practices

1. Status Practices
2. Safety Practices
3. Operator Inspection Tours
4. Round/Tour Inspection Sheets
5. Personnel Protection
6. Response To Indications
7. Resetting Protection Devices
8. Load Changes
9. Authority To Operate Equipment
10. Shift Operating Bases
11. Potentially Distractive Written Materials And Devices

Chapter III. Control Area Activities

1. Control Area Access
3. Monitoring The Main Control Boards
4. Control Operator Ancillary Duties
5. Operation Of Control Area Equipment

Chapter IV. Communications

1. Emergency Communications System
2. Public Address System
3. Contracting Operators
4. Radio
5. Abbreviations And Acronyms
6. Oral Instructions And Informational Communications

Chapter V. Control Of On-Shift Training

1. Adherence To Training Programs
2. On-Shift Instructor Qualification
3. Qualified Operator Supervision
4. Operator Qualification Program
5. Training Documentation
6. Suspension Of Training
7. Maximum Number Of Trainees

Chapter VI. Investigation Of Abnormal Events

1. Events Requiring Investigation
2. Investigation Responsibility
3. Investigator Qualification
4. Information To Be Gathered
5. Event Investigation
6. Investigative Report
7. Event Training
8. Event Trending
9. Sabotage Control Of Trainees

Chapter VII. Notifications

1. Notification
2. Notification Procedures Responsibility
3. Names And Phone Numbers
4. Documentation
5. Communication Equipment

Chapter VIII. Control Of Equipment And System Status

1. Status Change Authorization And Reporting
2. Equipment And System Alignments
3. Equipment Locking And Tagging
4. Operational Limits Compliance
5. Equipment Deficiency Identification And Documentation
6. Work Authorization And Documentation
7. Equipment Post-Maintenance Testing And Return To Service
8. Alarm Status
9. Temporary Modification Control
10. Distribution And Control Of Equipment And System Documents

Chapter IX. Lockouts And Tagouts

1. Lockout/Tagout Use
2. Lockout And Tagout Implementation
3. Protective Materials And Hardware
4. Lockout/Tagout Program
5. Procedures For Lockout/Tagout
6. Application Of Lockout/Tagout
7. Testing Or Positioning Of Equipment Or Components
8. Periodic Inspections
9. Caution Tags
10. Training And Communication
11. Lockout Or Tagout Implementation
12. Notification Of Personnel.
13. Outside Contractors
14. Group Lockouts Or Tagouts
15. Shift Or Personnel Change

Chapter X. Independent Verification

1. Components Requiring Independent Verification
2. Occasions Requiring Independent Verification
3. Verification Techniques

Chapter XI. Logkeeping

1. Establishment Of Operating Logs
2. Timeliness Of Recordings
3. Information To Be Recorded
4. Legibility
5. Corrections
6. Log Review
7. Care And Keeping Of Logs

Chapter XII. Operations Turnover

1. Turnover
2. Document Checklists Review
3. Control Panel Walkdown.
4. Discussion And Exchange Of
5. Shift Crew Briefing Responsibility
6. Reliefs Occurring During The Shift

Chapter XIII. Operations Aspects Of Facility Chemistry And Unique Processes

1. Operator Responsibilities
2. Operator Knowledge
3. Operator Response To Process Problems
4. Communicating Between Operations

Chapter XIV. Required Reading

1. File Index
2. Reading Assignments
3. Required Dates For Completion Of Reading
4. Documentation
5. Review

Chapter XV. Timely Orders To Operators

1. Content And Format
2. Issuing, Segregating, And Reviewing Orders
3. Removal Of Orders

Chapter XVI. Operations Procedures

1. Procedure Development
2. Procedure Content
3. Procedure Changes And Revisions
4. Procedure Approval
5. Procedure Review
6. Procedure Availability
7. Procedure Use

Chapter XVII. Operator Aid Postings

1. Operator
2. Approval
3. Posting Aid Development
4. Use Of Operator Aids
5. Documentation
6. Review

Chapter XVIII. Equipment And Piping Labeling

1. Components Requiring Labeling
2. Label Information
3. Label Placement
4. Replacing Labels

9.7 Elements of DOE Order 5480.22 - Technical Safety Requirements

DOE Order 5480.22¹²² defines Technical Safety Requirements as follows:

- (1) Use and Application. Definitions of terms, operating modes, frequency notations, and actions to be taken in the event of violation of Technical Safety Requirements operating limits or surveillance requirements are to be included in the Use and Application section. This section of the Technical Safety Requirements shall contain the basic instructions for using and applying the safety restriction contained in the Technical Safety Requirements.
- (2) Safety Limits (SL). Safety Limits are limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility function and which are found to be required to guard against the uncontrolled release of radioactivity and other hazardous materials (this includes releases into the complex and/or the community). If any Safety Limit is exceeded at any reactor or nonreactor nuclear facility, action shall begin immediately to place the facility in the most stable, safe condition attainable including total shutdown of either reactor or nonreactor nuclear facilities. The appropriate time frame for the completion of the action for each nuclear facility has to be developed and justified by the contractor, as appropriate, in the TSR document which requires PSO¹²³ approval. The SLs shall describe the action to be taken when an SL is exceeded.
- (3) Operating Limits.
 - (a) Limiting Control Settings (LCS). Limiting Control Settings are settings on safety systems that control process variables to prevent exceeding Safety Limits. This subsection of the Technical Safety Requirements shall contain the settings for automatic alarms and automatic or non-automatic initiation of protective actions related to those variables having significant safety functions. The specific settings shall be chosen such that if exceeded, sufficient time is available to automatically or manually correct the condition prior to exceeding Safety Limits. If the automatic alarms or protective devices do not function as required during applicable operating modes, the contractor shall take action as defined in the Limiting Control Setting to maintain the variables within the requirements and to promptly repair the automatic devices or the affected part of the process or, if required, the facility shall be placed in its most safe, stable condition. The LCS shall describe the action to be taken in case of exceedance of LCS.
 - (b) Limiting Conditions for Operation (LCO). Limiting Conditions for Operation are the lowest functional capability or performance level of safety-related structures, systems, component and their support systems required for normal safe operation of the facility. This subsection of the TSR shall contain the limits on functional capability or performance level. When a Limiting Condition for Operation is not met, the contractor shall take remedial actions defined by the Technical Safety Requirements until the condition can be met. The LCO shall describe the action to be taken in case of exceedance of the LCO.

¹²² DOE Order 5480.22, Technical Safety Requirements, p.9.

¹²³ Program Secretarial Officer (PSO) means the heads of DOE offices with responsibility for specific facilities. See earlier footnote for definition.

- (4) Surveillance. Surveillance Requirements are requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety-related structures, systems, components, and their support systems required for safe operation of the facility are maintained. This section of the Technical Safety Requirements shall contain the requirements necessary to maintain operation of the facility within the Safety Limits, Limiting Control Settings, and Limiting Conditions for Operations. In the event that Surveillance Requirements are not successfully completed or accomplished within their required frequency, the systems or components involved shall be assumed to be inoperative and actions defined by the Limiting Condition for Operation or Limiting Control Setting shall be taken until the systems or components can be shown to be operable.
- (5) Administrative Controls. Administrative Controls are the provisions relating to organization and management, procedures, recordkeeping, reviews, and audits necessary to ensure safe operation of the facility. This section of the Technical Safety Requirements shall contain the requirements associated with Administrative Controls including those for reporting deviations from Technical Safety Requirements (i. e., exceedances of LCO, LCS, or SR, or violation of TSR). Staffing requirements for facility positions important to safe operation of the facility shall be provided in the Administrative Controls sections. Physical and administrative controls of the criticality safety program shall also be provided in the Administration Controls section.
- (6) Appendices. The following information shall be in the Appendices:
- (a) Basis. This Appendix shall provide summary statements of the reasons for the operating limits and associated surveillance requirements. The basis shall show how the numeric value, the condition, or the surveillance does fulfill the purpose derived from the safety documentation. The primary purpose for describing the basis for each requirement will not affect its original intent or purpose.
 - (b) Design Features. This Appendix shall describe passive design features of the facility which, if altered or modified, would have a significant effect on safe operation. If Design Features are in a DOE-approved Safety Analysis Report, this Appendix is not required.

9.8 Excerpt from NRC Regulatory Guide 3.52 - Standard Format and Content Guide for the Health and Safety Sections of License Applications for Fuel Cycle Facilities, Revision 2 [DRAFT], January 1995.

Organization and Management of the Training System

Describe the performance based training system that is implemented as the primary management tool for developing, conducting, and evaluating training. Include with this a list of current training procedures with amplifications as needed. Provide a narrative of line management's involvement in the training system in determining and evaluating the content and conduct of training. Describe the responsibilities and authority of site personnel involved in managing, supervising, and implementing training. Provide a description on how training before initial qualification is determined. Describe the criteria used in granting exceptions from training and the maintenance and archiving criteria used for training records.

Trainee Selection

Describe the trainee selection process, including minimum education, technical, and experience requirements.

Conduct of Needs/Job Analysis and Identification of Tasks for Training

Describe the needs/job analysis process used in developing a facility specific task list. Describe how tasks selected for training are compared with existing training materials, to determine differences, to determine the adequacy of material coverage, and to identify needed improvements. Describe the method used to review and update the facility-specific task list.

Development of Learning Objectives as the Basis for Training

Describe how job performance requirements are used in developing learning objectives that are the basis for training and evaluation.

Organization of Instruction Using Lesson Plans and Other Training Guides

Describe the format used for developing lesson plans and training guides. Include the steps taken in the review and approval process.

Evaluation of Trainee Mastery of Learning Objectives

Describe how trainees are evaluated during training to determine their progress.

Conduct of On-the-Job Training

Describe how on-the-job training is implemented and conducted. Include how personnel who conduct on-the-job training are qualified and how consistency is maintained.

Systematic Evaluation of Training Effectiveness

Describe how the effectiveness of the training program is evaluated. Include the frequency of the evaluations, what elements are evaluated, and how the results are used to improve subsequent training.

9.9 Elements of DOE Order 5480.20 - Personnel Selection, Qualification, and Training Requirements for DOE Nuclear Facilities

1. Purpose. This Chapter provides specific requirements in addition to the general requirements of Chapter I for personnel at DOE non-reactor nuclear facilities.
2. Entry-Level Requirements. Entry-level requirements for operating organization personnel are intended to provide reasonable assurance that these personnel have, or can acquire, the knowledge and skills to operate and maintain the facility in a safe and reliable manner under all conditions. The following paragraphs describe the positions typically involved in the operation of non-reactor nuclear facilities, and the education and experience requirements for each.
 - a. Managers.
 - b. Supervisors.
 - c. Operators.
 - d. Technicians.
 - e. Maintenance Personnel.
 - f. Technical Staff.
 - g. Training Organization Personnel.
 - (1) Training Coordinators.
 - (2) Training Instructors.

3. Medical Examination Requirements. Operating contractor management shall determine the physical demands imposed upon operating organization personnel by the job tasks that are required to perform both routine and emergency functions. An initial medical examination shall be given to candidates and a reexamination shall be given at least every two years to certified operators, fissionable material handlers, and certified supervisors to verify health and physical fitness to safely perform their assigned tasks. Certified operators, fissionable material handlers, and certified supervisors must also be cleared by medical examination prior to returning to work following any illness or injury which keeps the individual from performing his or her duties for a period exceeding one month. Medical examination requirements for other operating organization personnel shall be in accordance with operating contractor procedures.
4. Specific Training Requirements. The depth and scope of training and qualification programs for operating organization personnel at non-reactor nuclear facilities shall be commensurate with the hazard level and complexity of the operations (i.e., a graded approach should be used to develop and implement the training programs). This section provides specific training requirements for operators, fissionable material handlers, and supervisors.
 - a. Operators.
 - b. Fissionable Material Handlers.
 - c. Supervisors.
 - d. Certified Operator Written Examination Contents.
 - e. Certified Supervisor Written Examination Contents.
 - f. Operational Evaluations.
 - g. Control Manipulations.
5. Operator, Fissionable Materials Handler, And Supervisor Proficiency Requirements. Certified operators, fissionable material handlers, and certified supervisors shall actively perform job functions associated with their certification to maintain proficiency. Actively performing job functions associated with certification means that the certified individual has a position on the shift crew, and that the individual carries out and is responsible for the day-to-day duties of the certified position. If certified operators, fissionable material handlers, or certified supervisors are absent from activities associated with the certified position for extended periods of time, their ability and readiness to perform at a high level of vigilance can reasonably be expected to decrease. The proficiency requirement is imposed to ensure that certified personnel continue to possess and practice the skills and abilities necessary to operate the systems and equipment for which they are responsible in a safe and reliable manner during both normal and abnormal facility operations and system transients.

9.10 Elements of DOE Order 4330.4B - Maintenance Management Program

The Reviewers may use the following as a tool when evaluating the Contractor's proposed maintenance implement plan outline.

10. Requirements

- a. The Maintenance Implementation Plan shall clearly define:
 - (1) The structures, systems, and components included, using a graded approach and the requirements derived from Technical Safety Requirements.
 - (2) The management systems used to control maintenance activities, including the means for monitoring and measuring the effectiveness of the program and the management of maintenance backlog.
 - (3) The assignment of responsibilities and authority for all levels of the maintenance organization.

- (4) Mechanisms for feedback of relevant information, such as trend analysis and instrumentation performance/reliability data, to identify necessary program modifications.
 - (5) Provisions for identification, evaluation, and correction of possible component, system design, quality assurance, or other relevant problems.
 - (6) Performance indicators and criteria to be utilized to measure equipment, systems, and personnel effectiveness in maintenance activities.
 - (7) Interfaces between maintenance and other organizations (i.e., operations, engineering, quality, training, environment, safety, and health).
 - (8) A self-assessment program to monitor the effectiveness and efficiency of the maintenance program.
 - (9) Provisions for planning, scheduling, and coordination of maintenance activities.
- b. Periodic inspections of structures, systems, components, and equipment, particularly those important to the safe and reliable operation of a facility, shall be performed to determine whether deterioration is taking place and to identify and address technical obsolescence that threatens performance, safety, or facility preservation. Where the potential is identified for any event or condition to significantly affect safety margins, a formal program for resolving the problem shall be documented and implemented. References in Paragraphs 5b and k apply.
- c. For DOE non-nuclear property, a graded approach utilizing the objectives and criteria provided in Chapter I shall be used in the development and implementation of Maintenance Programs
- d. For DOE nuclear facilities, a graded approach shall be used to determine the depth of detail required and magnitude of resources expended for each maintenance program element described in Chapter II. Sound engineering judgment and knowledge of the facility are essential in the application of the graded approach. For each DOE nuclear facility, the maintenance program shall be described in a Maintenance Implementation Plan, which addresses the 18 elements (excluding the introduction) in the sequence and format of Chapter II. DOE nuclear facility maintenance programs may include facility-related non-nuclear equipment provided the Maintenance Implementation Plan clearly identifies all equipment (or systems) and distinguishes those non-nuclear equipment/systems. For those DOE nuclear facilities where deviations from the maintenance program elements are considered necessary and appropriate (or not applicable), such deviations (or non-applicable elements) shall be identified in the Maintenance Implementation Plan with supporting rationale.
- e. Maintenance Implementation Plans for nuclear facilities shall be submitted to the Managers of field elements for approval. For new nuclear facilities, Maintenance Implementation Plans shall be submitted 90 days prior to startup. Changes to Maintenance Implementation Plans shall be submitted and approved prior to implementation.

9.11 Elements of DOE Order 5000.3B - Occurrence Reporting and Processing of Operations Information

The Reviewers may consider the following definitions and scope from DOE Order 5000.3B with regard to occurrence reporting.

Occurrence Report. A documented evaluation of an event or condition that is prepared in sufficient detail to enable the reader to assess its significance, consequences, or implications and to evaluate the actions being proposed or employed to correct the condition or to avoid recurrence.

Event. A real-time occurrence (e.g., pipe break, valve failure, loss of power, environmental spills, etc.)

Condition. Any as-found state, whether or not resulting from an event, which may have adverse safety, health, quality assurance, security, operational or environmental implications. A condition is more programmatic in nature, for example, an error in analysis or calculation; an anomaly associated with design or performance; or an item indicating a weakness in the management process are all conditions.

The Reviewers may assess the adequacy of the Contractor's outline using DOE Order 5000.3B as one acceptable standard. The elements of that Order are repeated below for Reviewers' convenience. The Reviewers may refer to the Order for additional detail if required for the review. The Contractor is not bound to either the Policy nor the specific authorities and responsibilities of DOE Officials described in the Order, but may wish to adopt similar ingredients in his proposed policy as well as to propose similar relationships with the Regulatory Unit.

It is the policy of the Department to encourage a positive attitude toward reporting occurrences and that occurrences be consistently reported to assure that both DOE and DOE contractor line management, including the Office of the Secretary, are kept fully and currently informed of all events which could: (1) affect the health and safety of the public; (2) seriously impact the intended purpose of DOE facilities; (3) have a noticeable adverse effect on the environment; (4) endanger the health and safety of workers; or (5) adversely affect national security or the security interests of the DOE. It is also the policy of the Department that there be a system for determining appropriate corrective action and for ensuring that such action is effectively taken. Specifically, it is DOE policy to ensure:

- a. Timely identification, categorization, notification, and reporting to DOE management of all Reportable Occurrences at DOE-operated facilities or DOE-owned, contractor-operated facilities;
- b. Timely evaluation of and implementation of appropriate corrective actions;
- c. Maintenance of a central DOE Occurrence Reporting and Processing System (ORPS) data base containing all unclassified Occurrence Reports;
- d. Review of Reportable Occurrences to assess significance, root causes, generic implications, and the need for corrective action; and
- e. Dissemination of Occurrence Reports to DOE operations and facilities to prevent similar occurrences.

Occurrence Categorization, Notification And Reporting Requirements

- a. Categorization
 1. Emergencies
 2. Unusual Occurrences
 3. Off-Normal Occurrences
- b. Notification
 1. Emergencies
 2. Unusual Occurrences
 3. Off-Normal Occurrences
 4. Categorization of Changes
- c. Follow-up Notification
- d. Occurrence Report Preparation
- e. Classification Requirements

Implementation Requirements

- a. Occurrence Categorization and Notification Process
- b. Occurrence Report and Follow-up Process
- c. Utilization of Reportable Occurrence Information
 - 1. Operational Data Base
 - 2. Utilization
- d. Procedures
- e. Training
- f. Exemption
- g. Documentation
- h. Implementation Schedule

9.12 Excerpts from Draft Rule 10 CFR 834.5 - Radiation Protection of the Public and the Environment, Subpart A, Section 5, “Environmental Radiological Protection Program”

An extract from the pertinent section of the Rule is summarized below for the Reviewers’ convenience and should be considered when evaluating the Contractor’s environmental radiological program outline.

The content of the Environmental Radiological Protection Program (ERPP) shall address each requirement of this part and include, but not be limited to, the following:

- (1) the identity of existing or anticipated DOE activities subject to the requirement;
- (2) the measures to be used in implementing the requirement;
- (3) the methods to be used in monitoring, reporting, and recording compliance with the requirement;
- (4) an As Low As is Reasonably Achievable (ALARA) Program [§834.104];
- (5) environmental monitoring [§834.7] including
 - (i) sources of airborne emissions [§834.201],
 - (ii) sources of emissions in liquid waste streams [§§834.211 and 834.212],
 - (iii) effluent monitoring [§834.7(b)(1)],
 - (iv) environmental surveillance [§834.7(b)(2)],
 - (v) meteorological data acquisition [§834.7(b)(3)], and
 - (vi) pre-operational monitoring [§834.7(b)(4)];
- (6) ground water protection [§834.215]; and
- (7) radiological protection in the management of radioactive waste [§834.221] and property containing residual radioactive material [subpart G].

9.13 Elements of DOE Notice 441.1 - Radiological Protection for DOE Activities

The general requirements from DOE Notice 441.1¹²⁴ are as follows:

- a. Administrative Control Levels - A system of administrative control levels (ACLs) shall be implemented to control radiological worker doses at levels below the occupational exposure limits provided in 10 CFR 835.202.
- b. Work Authorization - Authorizations to work in radiological areas shall be in accordance with the Radiological Protection Program, required by 10 CFR 835.101.

¹²⁴ DOE Notice 441.1, Radiological Protection for DOE Activities, 9/29/95.

- c. Radiation Safety Training - Radiation safety training for general employees, radiological workers, and radiological control technicians shall utilize those portions of the standardized core training materials published by DOE that are relevant to facility hazards and operations, augmented as necessary by site-specific materials.
- d. Posting - Any accessible area in which radioactive material is used, handled, or stored shall be posted with the words "Caution, Radioactive Material." The posting shall meet the requirements of 10 CFR 835.601.
- e. Control of Sealed Radioactive Sources - See Notice for detail if necessary.
- f. Exposure of Minors - The exposure of minors during direct on-site access to a DOE site or facility shall be controlled such that the dose to the extremities, lens of the eye, and other organs and tissues does not exceed 10% of the corresponding occupational exposure limits established in 10 CFR 835.202.
- g. DOE Laboratory Accreditation Program. The DOE Laboratory Accreditation Program (DOELAP) shall be maintained consistent with the applicable DOE standards, and dosimetry programs shall be accredited at periodic intervals consistent with the standards.

9.14 Oversight Process Determination

The purpose of this regulatory action is to monitor the operation of the Contractor's facility to ensure that the authorization basis and the conditions in the authorization agreement are not violated. The regulatory oversight program will consist of the following elements:

- 1. Annual review and assessment of physical, process, and operational changes;*
- 2. Annual review and assessment of site-related changes;*
- 3. Annual review and assessment of changes to equipment and structures, particularly those that are important-to-safety;*
- 4. Annual review and assessment of changes in the codes, standards, and regulations that form the authorization basis and the conditions in the authorization agreement;*
- 5. Annual review of the Contractor's analysis of the effects of the changes noted in items 1 - 4 above, including any analyses and determinations associated with potential unreviewed safety questions;*
- 6. Review and assessment of event reports;*
- 7. Review and assessment of the effectiveness of emergency response actions and drills;*
- 8. Review and assessment of the effectiveness of the Contractor's assessments of its conduct of operations;*
- 9. On-site inspections of records, premises, and activities, particularly those associated with conduct of operations;*

10. *Consideration of amendments to the authorization to operate or to the authorization agreement, including review and approval of changes to the FSAR;*
11. *Review and approval of proposed changes to the SRD and ISMP;*
12. *Review and approval of proposed changes to the TSRs;*
13. *Consideration of corrective actions, including suspension of operations; and*
14. *Communication of noncompliance's to the DOE Enforcement and Inspection staff for enforcement consideration under 10 CFR 820.*

This oversight function will be performed based on information submitted by the Contractor under oath and affirmation, on direct inspections, and on other reliable, documented information. The format and content for the information to be submitted by the Contractor will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action.

9.15 Deactivation Authorization Request Submittal Requirements

The ... Deactivation Authorization Request submittal package ... shall consist of the following documentation:

- 1) *A final deactivation plan;*
- 2) *Description of the post-operations conditions of the facility and the associated site;*
- 3) *Rationale for the selection of the deactivation approach;*
- 4) *The hazards assessment for the selected deactivation approach and the results;*
- 5) *Description of the controls and limits that will be imposed through procedures and on equipment to protect worker and public health and safety;*
- 6) *Description of the final radiation survey to be performed;*
- 7) *The funding commitments and arrangements for the deactivation activities, including final radiation survey and disposal of wastes; and*
- 8) *The proposed schedule for the deactivation and providing an assessment of the risks associated with any delays in performing the deactivation;*

10. ABBREVIATIONS

ACLs	Administrative Control Levels
ALARA	As Low As is Reasonably Achievable
CFR	Code of Federal Regulation
CM	Configuration Management
CORAMI	Constructability, Operability, Reliability, Availability, Maintainability, and Inspectability

DBEs	Design-Basis Events
DOE	Department of Energy
ERPP	Environmental Radiological Protection Program
FSAR	Final Safety Analysis Report
HAZOPs	Hazards and Operability
ISMP	Integrated Safety Management Plan
LCS	Limiting Control Settings
NRC	Nuclear Regulatory Commission
P&ID	piping and instrumentation diagrams
RAMI	Reliability, Availability, Maintainability, and Inspectability
RFP	TWRS Privatization Request for Proposal
RL	Richland Operations Office
RU	Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit)
SAP	Standards Approval Package
SL	Safety Limits
SRD	Safety Requirements Document
SSC	Structures, Systems, and Components
SSCs	Structures, Systems and Components
SSEs	Structures, Systems and Equipment
TWRS	Hanford Tank Waste Remediation System

11. GLOSSARY

Administrative Controls. Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Authorization Agreement. The document mutually agreed upon by the Director of the Regulatory Unit and a regulated Contractor that specifies authorization terms and conditions.

Common-Cause Failures. Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

Common-Mode Failures. Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

Controlled Area. The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the Contractor. The controlled area may include identified restricted areas.

Design.¹²⁵ The process and the result of developing the concept, detailed plans, supporting calculations and specifications for a nuclear facility and its parts.

¹²⁵ Derived from the definition of design used in IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance, 50-C-QA (Rev. 1).

Design Basis. The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Facility. Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

Graded Approach. A process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part are commensurate with:

- 1) The relative importance to safety, safeguards, and security;
- 2) The magnitude of any hazard involved;
- 3) The life cycle stage of a facility;
- 4) The programmatic mission of a facility;
- 5) The particular characteristics of a facility; and
- 6) Any other relevant factor.

Hazard. An inherent physical or chemical characteristic that has the potential for causing harm to people, property, or the environment. It is the combination of a hazardous material, an operating environment, and certain unplanned events that could result in an accident¹²⁶.

Hazard Assessment. As used in this Review Guide, Hazard Assessment comprises the approach outlined¹²⁷ in DOE Standard 3309.

Hazard Evaluation. The analysis of the significance of hazardous situations associated with a process or activity. Uses qualitative techniques to pinpoint weaknesses in the design and operation of facilities that could lead to accidents¹²⁸. Hazard Evaluation techniques include HAZOP Analysis, Fault and Event tree analysis, and other methods.

Important-to-Safety. Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction, i.e., support systems, subsystems, or components. Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important-to-safety, i.e., safety-related may be practical. However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

Integrated Safety Management Program. A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

Item. Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

¹²⁶ AICHE Guidelines, p. xxv.

¹²⁷ DOE-STD-3009-94.

¹²⁸ AICHE Guidelines, p. xxv.

Nonreactor Nuclear Facility. Those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Transportation of radioactive materials, accelerators and reactors and their operations are not included. The application of any rule to a nonreactor nuclear facility shall be applied using a graded approach.

Normal Operation. Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

Nuclear Facility. Reactor and nonreactor nuclear facilities.

Process. (Related to hazard) Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the on-site movement of such chemicals, or a combination of these activities.

Process. (Related to Quality Assurance) A series of actions that achieves an end or result.

Process Element. A component, subsystem, system, or region within of the facility. Each Contractor may define different process elements when performing their hazards evaluations.

Process Safety. The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

Public. Individuals who are not occupationally engaged at the Hanford Site.

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance. All those actions that provide confidence that quality is achieved.

Quality Assurance Program or QAP. The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Record. A completed document or other media that provides objective evidence of an item, service, or process.

Reliability Targets. Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period of time. Identified important-to-safety items are expected to perform their function satisfactorily through all design-basis accident conditions.

Requirements. Standards that are mandated by an authority through statute, regulation, or contract.

Safe State. A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

Safety Basis. The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the Director of the Regulatory Unit depends for its conclusion that activities at the facility can be conducted safely.

Safety Limits. Limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility safety functions and that are found to be required to prevent release of unacceptable levels of radioactive material to workers or the general public

Safety-related. The technical definition of “safety-related” often used in the DOE lexicon is intentionally not adopted. Instead, a broader definition is envisioned which umbrellas all activities, documentation, programs, equipment, etc. that have impacts on safety. As such, SSCs “important-to-safety” are a subset of that which is safety-related.

Safety Requirements Document. A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor’s facilities.¹²⁹

Service. The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Standards. The expressed expectation for the performance of work.

Standards Approval Package. The combined SRD and the ISMP submittal packages.

Submittal Requirement. Information required of the Contractors under the authority of the TWRS Privatization Contracts, and the four documents incorporated in the Contracts.

Technical Safety Requirements. Those requirements that define the conditions, the safe boundaries, and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality.

Unreviewed Safety Question (USQ). A safety question where any of the following conditions are satisfied: 1) the probability of occurrence or the radiological consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility analysis, may be increased; 2) a possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be created; or 3) any margin of safety is reduced. (Also see definition for "Margin of Safety.")

Worker. Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

Work Activities. All activities associated with performing the work including, design, construction, operation, and deactivation.

¹²⁹ *Regulatory Process*, Section 4.1.2, item 2, p.11.

Concurrence Page

Guidance for the Review of TWRS Privatization Contractor Initial Safety Assessment Submittal Package

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Regulatory Official Approval

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Note: Upon Regulatory Official (RO) approval, this concurrence page should be submitted along with the appropriate document(s) to the Information Management Coordinator (IMC) for final processing, publication, and dissemination.

Date sent to IMC: _____

By: _____